

IN GENERAL

Benaroya Research Institute oversees all clinical research at Virginia Mason and BRI, uniquely combining the expertise of a world-renowned biomedical research institute with the remarkable care of a healthcare quality leader.

BRI supports Virginia Mason clinical investigators in studies across a wide variety of diseases and conditions, such as cardiology and cancer, while the research led by BRI clinical investigators primarily focuses on diseases of the immune system such as type 1 diabetes, multiple sclerosis, rheumatic diseases, allergies and asthma.

The protocols listed in this booklet represent the major clinical trials approved by the Benaroya Research Institute Institutional Review Board for implementation by investigators at the Virginia Mason Medical Center. Information, protocols, consent forms and registration documents are available from these offices.

Alternatively, visit www.clinicaltrials.gov and enter the clinicaltrials.gov identifier listed for each study.

For questions, changes or additions to this booklet:

Marvey Erickson; (206) 342-6526 or

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Biorepositories (Translational Research)

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Main Line 1-877-202-5200

Biorepository@BenaroyaResearch.org

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ANESTHESIA

General Surgery

The effect of an opioid-free anesthetic on post-operative opioid consumption after laparoscopic bariatric surgery: a prospective, double-blinded, randomized controlled trial

Treatment Arm(s):

- A. Opioid based anesthetic regimen
- B. Opioid free anesthetic regimen

Select Inclusion Criteria:

- Adult (>18 years old)
- Patients undergoing elective laparoscopic gastric bariatric surgery (i.e. laparoscopic roux-en-Y gastric bypass, laparoscopic sleeve gastrectomy)
- Able to provide informed consent

Select Exclusion Criteria:

- Any opioid use within 4 weeks prior to surgery
- Chronic antiemetic use
- Hypersensitivity or contraindication to any study drug

Study ID: CRP19060

PI: Christine Oryhan, MD / CRC: Rachel Dowty / (206) 287-6275

Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org



The Allergy and Asthma Biorepository is a confidential list of people with allergies and asthma, who are willing to donate a blood sample and provide health information for scientific research. Donated samples and personal and family health information are used by scientists in the laboratory and in analysis to help us better understand the causes and long term health effects of allergies, asthma and immune-mediated diseases, as well as to explore better treatment options that can be used by physicians in patient care. All of the information gathered is kept confidential, and samples and health information used by scientists are coded with a number, not your name.

Participants are offered a \$50 reimbursement for their time and effort and a parking voucher for a Virginia Mason parking garage, as needed.

Select Inclusion Criteria:

We are currently enrolling children and adults, one year of age and older, with physician diagnosed food and environmental allergies. We are especially looking for people with a history of severe allergies and anaphylaxis.

We are also looking for friends and family members, who do not have an autoimmune disease, to join our healthy 'control' volunteer registry.

Contact: Translational Registry and Biorepository
Toll-free Line: 1-877-202-5200
Email: Allergy@BenaroyaResearch.org



BIOREPOSITORIES

Celiac Disease

The Celiac Disease Biorepository is a confidential list of people with celiac disease, who are willing to donate a blood sample and provide health information for scientific research. Donated samples and personal and family health information is used by scientists in the laboratory and in analysis to help us better understand the causes and long term health effects of gastrointestinal and immune-mediated diseases, as well as to explore better treatment options that can be used by physicians in patient care. All of the information gathered is kept confidential, and samples and health information used by scientists are coded with a number, not your name.

Participants are offered a \$50 reimbursement for their time and effort and a parking voucher for a Virginia Mason parking garage, as needed

Select Inclusion Criteria:

We are currently enrolling adults, age 18 and older, with a diagnosis of celiac disease.

We are also looking for friends and family members, who do not have an autoimmune disease, to join our healthy 'control' volunteer registry.

Contact: Translational Registry and Biorepository

Toll-free Line: 1-877-202-5200

Email: Gastro@BenaroyaResearch.org

BIOREPOSITORIES

Down Syndrome and Human Immunity



The Down Syndrome & Human Immunity Registry and Biorepository is a collaborative project between the BRI Translational Program and the Virginia Mason Down Syndrome Program, led by Rebecca Partridge, MD, PI, with co-investigators Bernard Khor, MD, PhD, and Jane Buckner, MD. The biorepository contains a confidential registry of individuals with and without autoimmune disease, who also have Down syndrome, and who are willing to donate biologic samples (e.g. blood).

People with Down syndrome have a significantly increased risk of getting autoimmune disease. BRI scientists are using donated samples and personal and family health information to better understand the relationship between Down syndrome and autoimmune disease. The main goal of this research is to identify new and better therapeutic targets to prevent and treat autoimmune diseases in people with Down syndrome, as well as the general population. The release of information and samples from the biorepository is governed by the BRI Institutional Review Board.

Participants are offered a \$50 reimbursement for their time and effort and a parking voucher is provided for a Virginia Mason parking garage, as needed.

Select Inclusion Criteria:

We are currently enrolling individuals with Down syndrome who have Type 1 Diabetes and Celiac Disease, as well as those who do not have an autoimmune disease. In the coming months we will begin enrolling individuals with other autoimmune diseases.

We are also looking for friends and family members who do and do not have autoimmune disease to join one of our autoimmune disease registries, as well as our healthy 'control' volunteer registry.

Contact: Translational Registry and Biorepository

Toll-free Line: 1-877-202-5200

Email: DSR@BenaroyaResearch.org



BIOREPOSITORIES

Healthy Volunteers without Autoimmune Disease

Individuals, age one year and older, who do not have an autoimmune disease and are generally in good health donate a blood sample and provide health information to Benaroya Research Institute (BRI) to support scientific research. Donated samples and personal and family health information is used by scientists in the laboratory and in analysis to help us better understand the causes and long term health effects of autoimmune and other diseases, as well as to explore better treatment options that can be used by physicians in patient care. Samples also allow scientists to study how a healthy immune system works in comparison to one that has disease. All of the information gathered is kept confidential, and samples and health information used by scientists are coded with a number, not your name.

Participants are offered a \$50 reimbursement for their time and effort and a parking voucher for a Virginia Mason parking garage, as needed.

Select Inclusion Criteria:

Individuals one year of age and older, who do not have an autoimmune disease, may be eligible to join the registry.

Contact: Translational Registry and Biorepository

Toll-free Line: 1-877-202-5200

Email: Control@BenaroyaResearch.org



Sound Life Project

This is a research study about understanding the immune system and learning why disease does and does not happen in people. We are asking healthy adults, between the ages of 25-35 and 55-65 to join this study, allowing us to observe the immune system and its responses over time. Participants are offered a \$50 reimbursement for their time and effort and a parking voucher for a Virginia Mason parking garage, as needed.

Select Inclusion Criteria:

- Willing to donate blood to research
- Have personal iPhone or Android cell phone to download and use the health application
- Do NOT have any history of cancer, other than non-Melanoma skin cancers
- Do NOT have a chronic viral infection such as Hepatitis B, C, HIV/AIDS
- Have NOT had a major surgery in the past year
- NOT Anemic
- Do NOT have a first-degree relative with Rheumatoid Arthritis, Lupus, or Inflammatory Bowel Disease
- Do NOT use intravenous drugs

Contact: Translational Registry and Biorepository
Toll-free Line: 1-877-202-5200
Email: SoundLifeProject@BenaroyaResearch.org



BIOREPOSITORIES

Infectious Diseases and Vaccines

The Infectious Diseases and Vaccines Registry and Biorepository is a collaborative project between the BRI Translational Program and Virginia Mason's Department of Infectious Disease. The study contains a confidential registry of individuals who are willing to participate in vaccine studies, have had a viral infection, or are planning to travel to or have lived in a tropic virus risk area. Study participants provide health information and donate a blood sample. The donated samples and health information are used by scientists in the laboratory to better understand the causes and long-term health effects of infectious and bacterial diseases and how the immune system functions. The release of information and samples from the biorepository is governed by a clinical protocol that is approved and reviewed annually by the BRI Institutional Review Board.

Select Inclusion Criteria:

Adults age 18 years and older with no history of autoimmune disease and who:

- Are planning on getting a vaccine, such as influenza, tetanus, shingles, Yellow Fever, Japanese Encephalitis, etc.
- Have lived in a tropical virus risk area for 10 or more years, such as in India or a Southeast Asian country

Contact: Translational Registry and Biorepository

Toll-free Line: 1-877-202-5200

Email: IDR@BenaroyaResearch.org

BIOREPOSITORIES

Inflammatory Bowel Disease



The Inflammatory Bowel Disease Registry and Biorepository is a confidential list of people with inflammatory bowel diseases (IBD), such as Crohn's disease and ulcerative colitis, who are willing to donate a blood sample and provide health information to support scientific research. Donated samples and personal and family health information are used by scientists in the laboratory and in analysis to help us better understand the causes and long term health effects of gastrointestinal and immune-mediated diseases, as well as to explore better treatment options that can be used by physicians in patient care. All of the information gathered is kept confidential, and samples and health information used by scientists are coded with a number, not your name.

Participants are offered a \$50 reimbursement for their time and effort and a parking voucher for a Virginia Mason parking garage, as needed.

Select Inclusion Criteria:

We are currently enrolling adults, age 18 and older, with known or suspected history of inflammatory bowel disease.

We are also looking for friends and family members, who do not have an autoimmune disease, to join our healthy 'control' volunteer registry.

Contact: Translational Registry and Biorepository

Toll-free Line: 1-877-202-5200

Email: Gastro@BenaroyaResearch.org



BIOREPOSITORIES

Multiple Sclerosis

The Multiple-Sclerosis – Neurological Diseases Registry and Biorepository is a collaborative project between the BRI Translational Program and the Virginia Mason Neurosciences Institute. The biorepository contains a confidential registry of individuals with multiple sclerosis (MS) or other neurologic diseases who are willing to provide personal and family health information to the registry and tissue samples (e.g., blood, CSF) to the repository. The samples and health information are used by scientists in the laboratory to better understand the causes and long-term health effects of MS and other immune-mediated neurologic diseases, as well as explore better treatment options that can be used by physicians in patient care. The release of information and samples from the biorepository is governed by a clinical protocol that is approved and reviewed annually by the BRI Institutional Review Board.

Participants are offered a \$50 reimbursement for their time and effort and a parking voucher for a Virginia Mason parking garage as needed

Select Inclusion Criteria:

We are currently enrolling adults, age 18 and older, with a diagnosis of multiple sclerosis who are and are not receiving immune modulating treatment.

We are also looking for friends and family members, who do not have an autoimmune disease, to join our healthy ‘control’ volunteer registry.

Contact: Translational Registry and Biorepository

Toll-free Line: 1-877-202-5200

Email: Neuro@BenaroyaResearch.org

BIOREPOSITORIES

Recovered COVID Postive Study



We are enrolling participants that had tested positive for SARS-covid19, but have since recovered and are out four weeks or more from having symptoms. The study is longitudinal, but the time points may differ.

Participants will be asked to donate blood and health information with a \$50 reimbursement for each blood donation visit, as with our other studies.

Contact: Translational Registry and Biorepository
Toll-free Line: 1-877-202-5200
Email: Covid@BenaroyaResearch.org



BIOREPOSITORIES

COVID Vaccine Study

We are enrolling subjects with and without autoimmune disease, who are receiving the Pfizer or Moderna vaccine as part of their standard of care, to participate in a pre and post vaccine study.

Please note; we will not be administering the vaccine as part of this study.

Inclusion/Exclusion criteria will fluctuate a bit depending on the investigator's requests so we will be determining that during screening.

Contact: Translational Registry and Biorepository
Toll-free Line: 1-877-202-5200
Email: BRICovidResearch@BenaroyaResearch.org



The Rheumatic Disease Registry and Biorepository is a collaborative project between the BRI Translational Program and Virginia Mason's Department of Rheumatology. The biorepository contains a confidential registry of individuals with rheumatic diseases (e.g., rheumatoid arthritis, systemic lupus erythematosus) who are willing to provide personal and family health information to the registry and donate tissue samples (e.g., blood) to the repository. The donated samples and health information is used by scientists in the laboratory to better understand the causes and long-term health effects of rheumatic and other immune-mediated diseases, as well as explore better treatment options that can be used by physicians in patient care. The release of information and samples from the biorepository is governed by a clinical protocol that is approved and reviewed annually by the BRI Institutional Review Board.

Participants are offered a \$50 reimbursement for their time and effort and a parking voucher for a Virginia Mason parking garage, as needed.

Select Inclusion Criteria:

Adults diagnosed with a rheumatic disease. We have a particular interest in obtaining samples from participants that are not on medication and those willing to give a sample when they are having a flare. Our current areas of study include:

- Rheumatoid Arthritis (RA)
- Systemic Lupus Erythematosus (SLE)

We are also looking for friends and family members, who do not have an autoimmune disease, to join our healthy 'control' volunteer registry.

Contact: Translational Registry and Biorepository

Toll-free Line: 1-877-202-5200

Email: RDR@BenaroyaResearch.org



BIOREPOSITORIES

Type 1 Diabetes

The Diabetes Biorepository is a confidential list of people with type 1 diabetes who donate a blood sample and provide health information for scientific research. We invite you to participate in this research study to help us improve our understanding of diabetes and immune mediated diseases. The BRIDGE study was previously known as the JDRF Natural History study. The study consists of a computer registry where we store your contact, research and health information and a sample repository where we keep blood and other biologic samples for current and future use in our research.

Select Inclusion Criteria:

We are currently enrolling individuals with Type 1 Diabetes

Contact: BRI Diabetes Clinical Research Program

Toll-free Line: 1-800-888-4187

Email: Diabetes@BenaroyaResearch.org



A Cancer Registry and Specimen Repository developed to support ongoing and future research projects at Virginia Mason and BRI.

The VM BRITE Tissue Repository and Registry is designed to support ongoing studies and future studies by researchers at BRI, VM Medical Center, and their collaborators. The overall goal of these studies is to improve our knowledge of cancer using a combination of molecular, biochemical, and cellular approaches. More specifically, these studies will contribute to our understanding of the role the immune system plays in tumor development, tumor growth, and response to therapy. This research requires access to blood and/or tissue samples from people with the underlying disease(s) being studied. The release of information and samples from the biorepository is governed by a clinical protocol that is approved and reviewed annually by the BRI Institutional Review Board.

Select Inclusion Criteria:

Any tumor is a potential specimen for VM-BRITE. VM Pathology will retain adequate tissue for clinical purposes and release remaining tissue to VM-BRITE. Additionally, a blood draw (25-50 mL) will be required on the day of surgery for isolation of peripheral blood mononuclear cells and serum.

Study ID: IRB14138

PI: Christopher Gault, MD / CRC: Rachel Dowty / (206) 287-6275

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BIOREPOSITORIES

VM-BRIDPAN

VM-BRI Repository For Early Detection Of Pancreas Cancer

As part of a national consortium effort to develop and test new molecular and imaging biomarkers to detect early stage PDAC and its precursor lesions and through a primary award to the Buffett Cancer Center at the University of Nebraska Medical Center (UNMC), we plan to develop a repository (the VM-BRIDPAN Registry) of serially collected, well annotated samples and selected clinical data from patients with benign and malignant diseases of the pancreas. This effort will contribute to a foundational dataset for discovery and evaluation of early detection markers for pancreas cancer.

Select Inclusion Criteria:

Age 21 and older and 1 or more of the following:

- Referral for suspected benign cystic lesions of the pancreas.
- Referral for surveillance or resection of previously diagnosed benign pancreatic neoplasms.
- Referral for suspected or confirmed pancreas cancer.
- Referral for suspected or confirmed pancreatitis.
- Referral for familial risk including familial pancreatic cancer mutations.
- NO Chemotherapy < 1 year prior to enrollment and/or sample collection
- NO Known anemia (hemoglobin < 10 g/dl)

Study ID: CRP18084

PI: Margaret Mandelson, PhD / CRC: Meagan Cavanagh / (206) 287-6277 / Meagan.Cavanagh@VirginiaMason.org



Connect® MDS/AML Disease Registry

This Disease Registry will collect data on patient characteristics, treatment patterns and clinical outcomes. The objective is to describe how newly diagnosed MDS, ICUS or AML patients are treated; and to build a knowledge base regarding the effectiveness and safety of front-line and subsequent treatment regimens in both community and academic settings. Enrolled patients will receive treatment and evaluations for MDS, ICUS or AML according to the standard of care and routine clinical practice at each study site. All treatments that patients receive for MDS, ICUS or AML will be recorded, including initial treatment and any subsequent therapy. Data on treatment outcomes, including response rates as measured by the treating physician, evidence of progression, survival, and patient-reported outcomes will be collected quarterly on the electronic CRF.

Select Inclusion Criteria:

- Newly diagnosed (confirmed diagnosis within 60 days prior to date of informed consent signature), primary or secondary Myelodysplastic Syndromes (MDS), or Acute Myeloid Leukemia (AML), or Idiopathic Cytopenia of Undetermined Significance (ICUS)
- AML patients must be at least 55 years of age at the time of informed consent signature
- MDS/ICUS patients must be at least 18 years of age at the time of informed consent signature.

NIH Site: clinicaltrials.gov/ct2/show/NCT01688011

Study ID: IRB13104

PI: David Aboulafia, MD/ CRC: Anas Najjar / (206) 287-6271

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Immune-Mediated Diseases and Tumor Registry and Repository

The immune system is responsible for protecting us from infectious disease and abnormal or diseased cells. Cancer cells can be destroyed by the immune system, but many cancer cells use ways to avoid being detected, allowing their growth to go unchecked. A new class of drugs, called “immune checkpoint inhibitors,” overcomes the main defense that some cancer cells have, allowing the immune system to attack and destroy them. The Immune Checkpoint Inhibitor (ICI) Cancer Research Study is designed to look at blood samples obtained from patients who will be receiving treatment with marketed checkpoint inhibitors. Blood samples from patients receiving immune checkpoint inhibitors will be stored in the Immune-Mediated Diseases and Tumor Registry and Repository. A comparison of longitudinally obtained matched blood samples from before and after treatment and, where available, tumor tissue, will enable us to characterize the immune cells responsible for attacking the tumor and to look for associated biomarkers for cancer and response to therapy.

Select Inclusion Criteria:

- Patients who have a malignancy that will be treated using checkpoint inhibitors, either alone or in combination with other treatments
- Patients who are at least 18 years old
- Patients who have signed the approved informed consent

Study ID: CRP17064

PI: John Paul Flores, MD / CRC: Rachel Dowty / (206) 287-6275

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Checkpoint Inhibitors and T Cells Response

Immune checkpoint inhibitor (ICI) therapies have revolutionized the field of solid tumor oncology — in particular, PD-1 ICIs have played a substantial role in improving the survival of patients with advanced lung, head and neck, and urothelial cancer. These common carcinogen-related cancers of the lung, head and neck, and genito-urinary system cause tremendous morbidity and mortality. In fact, lung cancer is the second most prevalent cancer and the leading cause of cancer-related death (1). Historical survival is poor in the advanced setting of these cancers, and cure rates are low even at earlier stages. However, not only have durable responses been observed, but remissions and improvement in overall survival with anti-PD-1 and anti-PD-L-1 antibodies have been notable in these cancer types.

Select Inclusion and Exclusion Criteria:

- Adults over age 18 with a diagnosis of advanced (defined as metastatic or locally advanced/unresectable) NSCLC, UC, and HNSCC who have not previously received but will be treated with any PD-(L)1 agent (either singly or in combination) including: pembrolizumab, nivolumab, cemiplimab, atezolizumab, avelumab, or durvalumab, or other anti-PD(L)1 agent.
- Patients must have a hemoglobin level ≥ 9.0 g/dL without need for PRBC transfusion within the last week prior to study enrolment.
- Patients who have been previously treated with ICI, including inhibitors to CTLA-4 (e.g., ipilimumab) would be ineligible.
- Patients who are medically unable to provide additional blood for research.

Study ID: CRP20016

PI: John Paul Flores, MD / CRC: Rachel Dowty / (206) 287-6275

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CANCER

Bladder

Pembrolizumab in Treating Patients With Locally Advanced Bladder Cancer (AMBASSADOR)

Treatment Arm(s):

- A. Observation
- B. pembrolizumab

Select Inclusion Criteria:

- Histologically confirmed muscle-invasive urothelial carcinoma of the bladder or upper tract; variant histology allowed as long as urothelial carcinoma is predominant
- Patient must fit into one of the following three categories:
 - Patients who received neoadjuvant chemotherapy and pathologic stage at surgical resection is \geq pT2 and/or N+ OR
 - Patients that decline adjuvant cisplatin-based or other systemic chemotherapy based on an informed discussion with the physician and pathologic stage at surgical resection is \geq pT3 or pN+
- Patient must have had radical surgical resection of their bladder cancer \geq 4 weeks but \leq 16 weeks prior to pre-registration
- No invasive cancer at the surgical margins

NIH Site: clinicaltrials.gov/ct2/show/NCT03244384

Study ID: CRP19006

PI: John Paul Flores, MD / CRC: Karolina Rauch / (206) 287-6279

Pager: (206) 314-0118 / Karolina.Rauch@VirginiaMason.org



Does the Use of a Post-Operative Pedometer Impact the Return of Bowel Function and Narcotic Use Following Radical Cystectomy?

Treatment Arm(s):

- A. Combination Therapy: MEDI4736 (Durvalumab) + Tremelimumab
- B. Monotherapy: MEDI4736 (Durvalumab)
- C. Active Comparator: Standard of Care: Cisplatin, Carboplatin, Gemcitabine

Select Inclusion Criteria:

- Men and women age 18-75
- Must be undergoing radical cystectomy for bladder cancer at Virginia Mason Medical Center
- Patients both with and without neo-adjuvant chemotherapy will be included in the study

Exclusion Criteria:

- Long-term opioid use, defined by CDC as use of opioids on most days for >3 months
- History of inflammatory bowel disease
- Prior abdominopelvic radiation
- Concurrent surgery during radical cystectomy
- Gastroparesis or other baseline bowel dysmotility issues

Study ID: CRP19119

PI: John Corman, MD / CRC: Marina Jovic / (206) 287-6282

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CANCER

Bladder

A Prospective, Non-Interventional Study to Assess the Prevalence of PD-L1 Expression in the First-Line Setting of Locally Advanced/Unresectable or Metastatic Urothelial Carcinoma

Primary Objective(s):

The primary objective is to assess the prevalence of pre-treatment tumor tissue PD-L1 high expression in the 1L setting in advanced UC patients (locally advanced/unresectable or metastatic) using the Ventana SP263 assay.

Select Inclusion and Exclusion Criteria:

- Age \geq 18 years old
- Patients with histologically-confirmed diagnosis of UC and health-care provider (HCP)-confirmed advanced UC prior to or during 1L therapy (primary histology UC; mixed histologies are allowed).
- Patients with available tumor tissue sample (fresh or archival – up to 3 years old) that was collected as part of SoC any time prior to 1L treatment for advanced UC with a target of 18 slides available for biomarker testing (PD-L1 and tTMB).
- Patients with history of non-urothelial active malignancy that completed therapy within 2 years from study enrollment except:
 - Any resected in situ carcinoma or non-melanoma skin cancer
 - Localized (early stage) cancer treated with curative intent (with out evidence of recurrence and intent for further therapy) and in which no systemic therapy was

NIH Site: clinicaltrials.gov/ct2/show/NCT03788746

Study ID: CRP19051

PI: John Paul Flores, MD / **CRC:** Karolina Rauch / (206) 287-6279

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A Randomized Phase II/III Open-Label Study of Ipilimumab and Nivolumab Versus Temozolomide in Patients With Newly Diagnosed MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Unmethylated Glioblastoma

Treatment Arm(s):

- A. Arm I (radiation therapy, temozolomide)
Patients undergo radiation therapy over 30 fractions for 5 days per week (Monday-Friday) and receive temozolomide PO daily for 6 weeks. After radiation, patients may wear the Optune device at the discretion of the patient and their treating physician. Beginning 1 month after radiation therapy, patients receive temozolomide on days 1-5. Treatment repeats every 28 days for up to 12 cycles at the discretion of the treating investigator in the absence of disease progression or unacceptable toxicity.
- B. Arm II (radiation therapy, ipilimumab, nivolumab)
Patients undergo radiation therapy over 30 fractions for 5 days per week (Monday-Friday) for 6 weeks. Starting on the first day of radiation, patients also receive ipilimumab IV over 90 minutes Q4W for 4 doses and nivolumab IV over 30 minutes every 2 weeks until disease progression.

Select Inclusion Criteria:

- No known IDH mutation.
- Availability of formalin-fixed paraffin-embedded (FFPE) tumor tissue block and hematoxylin & eosin (H&E) stained slide to be sent for central pathology review for confirmation of histology and MGMT promoter methylation status.
- Contrast-enhanced brain MRI within 72 hours after surgery

NIH Site: clinicaltrials.gov/ct2/show/NCT04396860

Study ID: CRP20076

PI: Huong Pham, MD / CRC: Rachel Dowty / (206) 287-6275

Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org



CANCER

Breast

Breast Cancer Conserving Therapy

A Intra-Operative Radiotherapy after breast conserving therapy in the treatment of in situ and early stage breast cancer

Treatment Arm(s):

- A. IORT Administration

Select Inclusion and Exclusion Criteria:

- Have ductal carcinoma-in-situ, pleomorphic lobular carcinoma-in-situ, invasive ductal carcinoma, invasive lobular carcinoma, or other variants of invasive breast carcinoma
- Have a unifocal lesion ≤ 3.0 centimeters on any imaging study. Patients with lobular histology muDebrast have lesions ≤ 3.0 seen on MRI
- Are candidates for partial mastectomy
- Have clinically and radiographically benign-appearing lymph nodes
- ≥ 45 years of age
- No scleroderma, systemic sclerosis and active lupus
- No previous ipsilateral radiation to the thorax or breast
- No participation in an investigational drug or device study
- No multifocal breast cancer or Neoadjuvant systemic therapy
- Premenopausal patients over the age of 45, who are of pregnancy potential, will have a preoperative serum beta HCG done to ensure the patient is not pregnant

NIH Site: clinicaltrials.gov/ct2/show/NCT02266602

Study ID: IRB11143

PI: Michelle Yao, MD / CRC: Kathlyn Acosta / (206) 287-6265

Pager: (206) 314-0460 / Kathlyn.Acosta@VirginiaMason.org



PACES: A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon Cancer, Phase III – Preventing Adenomas of the Colon with Eflornithine and Sulindac

Treatment Arm(s):

- A. eflornithine placebo + sulindac placebo
- B. eflornithine + sulindac placebo
- C. eflornithine placebo + sulindac
- D. eflornithine + sulindac

Select Inclusion and Exclusion Criteria:

- Patients must have a history of Stage 0, I, II or III colon cancer that has been treated with resection alone or in combination with adjuvant chemotherapy.
- Must be registered between 274-465 days of primary resection.
- Must NED by postop colonoscopy and CT scans at least 274 days after resection.
- Must not have cardiovascular risk factors including uncontrolled high blood pressure, unstable angina, or history of MI or CVA.
- Patients must not be receiving or plan to receive concomitant corticosteroids, NSAIDs, or anticoagulants on a regular basis.
- Patients must not be expecting to receive radiation or additional chemotherapy.

NIH Site: clinicaltrials.gov/ct2/show/NCT01349881

Study ID: IRB15083

PI: Bruce Lin, MD / CRC: Rachel Dowty / (206) 287-6275

Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org



CANCER

Colorectal

Randomized Trial of Standard Chemotherapy Alone or Combined With Atezolizumab as Adjuvant Therapy for Patients With Stage III Colon Cancer and Deficient DNA Mismatch Repair

Treatment Arm(s):

Patients receive oxaliplatin IV over 2 hours and leucovorin calcium IV over 2 hours on day 1, and fluorouracil IV as a bolus on day 1, then continuously over 46 hours on days 1-3. Treatment repeats every 14 days for up to 12 cycles in the absence of disease progression or unacceptable toxicity. Patients also receive atezolizumab IV over 30-60 minutes starting on day 1 of cycle 1 or 2. Treatment repeats every 14 days for up to 25 cycles in the absence of disease progression or unacceptable toxicity.

Select Inclusion and Exclusion Criteria:

- Histologically proven stage III colon adenocarcinoma (any T [Tx, T1, T2, T3, or T4], N1-2M0; includes N1C); tumors must be deemed to originate in the colon including tumors that extend into/involve the small bowel (e.g. those at the ileocecal valve)
- Patients who are known to have Lynch syndrome and have been found to carry a specific germline mutation in an MMR gene (MLH1, MSH2, MSH6, PMS2) are eligible to participate
- No prior medical therapy (chemotherapy, immunotherapy, biologic or targeted therapy) or radiation therapy for the current colon cancer except for one cycle of mFOLFOX6
- No known active hepatitis B or C

NIH Site: clinicaltrials.gov/ct2/show/NCT02912559

Study ID: CRP19009

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A Pilot Protocol Evaluating Safety of the Medtronic Pump and Codman Catheter for the Delivery of Hepatic Arterial Infusion (HA I) Chemotherapy in patients with advanced Colorectal Carcinoma or Cholangiocarcinoma

Treatment Arm(s):

A. Experimental: Pump Therapy

All patients will undergo surgery to have the Medtronic pump and Codman catheter placed appropriately before HAI therapy can begin

Select Inclusion Criteria:

- History of histologically confirmed colorectal adenocarcinoma metastatic to the liver with no clinically or radiographically confirmed extrahepatic disease (or) Histologically confirmed cholangiocarcinoma (Clinical or radiographic evidence of metastatic disease that has been resected is allowed, provided there is no recurrence in that area prior to protocol consent)
- Participants ≥ 18 years of age
- ECOG ≤ 1

Exclusion Criteria

- Prior radiation to the liver (prior radiation therapy to the pelvis is acceptable if completed at least 4 weeks prior to the planned first dose of treatment on protocol)
- Colorectal cancer that is BRAF mutant or defective in mismatch repair.

NIH Site: clinicaltrials.gov/ct2/show/NCT04668976

Study ID: CRP19045

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CANCER

Colorectal

SHORT: SHOrt course Radiation and TASOX (TAS102 plus Oxaliplatin) chemotherapy in operable rectal cancer, a phase II trial.

Treatment Arm(s):

Patients are initially treated with 25 Gy in five fractions of 5 Gy conformal pelvic radiation. Radiation is to be started within 3 weeks of registration. TASOX should be commenced within 3 weeks of radiation completion. Patients are treated with 6 x 14 day cycles of TASOX. Within 4 weeks of the end of cycle #6 of TASOX patients undergo re-staging. Surgery should be performed within 4 weeks AFTER day 14, cycle#6 of TASOX, ie. 28 days after day 14, cycle 6.

Select Inclusion and Exclusion Criteria:

- Age of at least 18 years.
- Newly diagnosis of rectal adenocarcinoma.
- ECOG Performance Status (PS): 0, 1 or 2.
- Candidate for sphincter-sparing surgical resection prior to initiation of neoadjuvant therapy according to the primary surgeon.
- Clinical Stage: T1/N1, T2/N1, T3/N1, T3c/dN0 .
- Absence of metastatic disease.

Study ID: CRP18085

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A Randomized Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors Compared to a Healthy Living Education Control: A Feasibility and Preliminary Efficacy Study (AIMS-RC)

Treatment Arm(s):

- A. Experimental: Arm I (diet modification coaching, motivational messages)
- B. Active Comparator: Arm II (standard of care, motivational messages)

Select Inclusion Criteria:

- 18 Years and older
- Patients must have prior history of rectosigmoid colon cancer or rectal cancer
- Patients who are currently undergoing treatment for another cancer will have a different symptom profile than what this study is targeting and are not eligible
- Patients who have been diagnosed with inflammatory bowel disease (IBD), such as ulcerative colitis or Crohn's disease, are not eligible
- Patient must be registered to step 2 no more than 40 days after step 1 registration. If day 40 falls on a weekend or holiday, the limit may be extended to the next working day

NIH Site: clinicaltrials.gov/ct2/show/NCT04205955

Study ID: CRP20058

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CANCER

Esophageal

Temporal Variation in Exhaled Volatile Organic Compounds in Response to Therapeutic Intervention in Esophageal Cancer Patients

Primary objective(s):

- A. To determine longitudinal variation in exhaled VOC concentration during intended curative therapy for esophageal cancer (EC)
- B. To correlate the exhaled VOCs of EC patients to important clinical parameters

Select Inclusion Criteria:

- aged 18-90 years
- newly diagnosed, treatment naive patients with esophageal and/or gastroesophageal junctional cancer
- planning to undergo curative treatment including neoadjuvant chemoradiotherapy and surgical resection

Select Exclusion Criteria:

- pregnant females
- without malignant esophageal disease
- patients undergoing palliative treatment for esophageal cancer
- patients not receiving neoadjuvant chemoradiotherapy and surgical resection for EC
- Inability or unwillingness to provide written informed consent

Study ID: CRP19015

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Evaluation of the Lasting Symptoms After Esophageal Resection (LASER) questionnaire in esophageal disease

Primary Objective(s):

The primary objective of this project is to improve the care for patients that are treated for diseases of the esophagus at the General and Thoracic Surgery Department at the Virginia Mason Medical Center (VMMC). Secondary aims include; increased patient involvement and satisfaction, simplified data gathering of patient related outcomes (PRO) and improved clinical research and follow up of the included conditions.

Select Inclusion Criteria:

- Any patients, ≥ 18 years old, referred to the Thoracic Surgery Department for evaluation.
- Patients undergoing endoscopic therapies who are cared for jointly by both the surgical and gastroenterology teams.

Study ID: CRP18103

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CANCER

Esophageal

Phase 2 Study of ZW25 Plus First-Line Combination Chemotherapy in HER-2Expressing Gastroesophageal Adenocarcinoma (GEA)

Treatment Arm(s):

- A. ZW25 plus fluorouracil (5-FU) and cisplatin
- B. ZW25 plus 5-FU, leucovorin, and oxaliplatin
- C. ZW25 plus capecitabine and oxaliplatin
- D. ZW25 plus 5-FU, leucovorin, oxaliplatin, and bevacizumab
- E. ZW25 plus cisplatin and gemcitabine

Select Inclusion Criteria:

- Part 1: GEA: Unresectable, locally advanced, recurrent or metastatic HER2-expressing GEA (IHC 3+ or 2+ with or without gene amplification based upon local assessment or central assessment)
- Part 2: GEA: Unresectable, locally advanced, recurrent or metastatic HER2-expressing GEA (IHC 3+, or IHC 2+ and FISH+ by central assessment)
- An Eastern Cooperative Oncology Group (ECOG) Performance Status score of 0 or 1

Select Exclusion Criteria:

- Prior treatment with a HER2-targeted agent
- Patients with certain contraindications to bevacizumab cannot be enrolled on the mFOLFOX6-2 with bevacizumab arm.
- Palliative radiotherapy is allowed if completed at least 2 weeks prior to first study treatment dosing
- Clinically significant interstitial lung disease

NIH Site: clinicaltrials.gov/ct2/show/NCT03929666

Study ID: CRP19005

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A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients With Newly Diagnosed Germ Cell Tumors

Treatment Arm(s):

- A. Observational (blood collection)
Patients undergo collection of blood every 3-6 months for up to 3 years.

Select Inclusion Criteria:

- Patients must have a new diagnosis of a germ cell tumor. confirmed pathologically or serologically (diagnostic elevation of human chorionic gonadotropin [HCG]/alpha-fetoprotein [AFP]). All primary sites, stages, histological subtypes of germ cell tumor are eligible. Metachronous second primary germ cell tumors are eligible
- If surgery is planned, male patients with clinical stage I testicular cancer must have orchiectomy completed within 42 days prior to registration
- Patients must have risk of relapse assessment determined by the local investigator prior to registration
- Patients must be offered participation in specimen banking for future research. With patient's consent, specimens must be submitted.
- Patients must be informed of the investigational nature of this study and must sign and give written informed consent in accordance with institutional and federal guidelines

NIH Site: clinicaltrials.gov/ct2/show/NCT04435756

Study ID: CRP20073

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CANCER

Hepatobiliary Malignancies

A Phase III Open-Label, Multi-Centre, Randomized Study Comparing NUC-1031 Plus Cisplatin to Gemcitabine Plus Cisplatin in Patients With Previously Untreated Locally Advanced or Metastatic Biliary Tract Cancer

Treatment Arm(s):

- A. Experimental: A - NUC-1031 and cisplatin
- B. Active Comparator: B - gemcitabine and cisplatin

Select Inclusion Criteria:

- Female or male patients aged ≥ 18 years.
- Life expectancy ≥ 16 weeks.
- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1.
- QTc interval < 450 msec (males) or < 470 msec (females), in the absence of bundle branch block. In the presence of bundle branch block with consequent QTc prolongation, patients may be enrolled based on a careful risk-benefit assessment.

Exclusion Criteria:

- Combined or mixed hepatocellular/cholangiocarcinoma.
- Symptomatic central nervous system or leptomeningeal metastases.
- Concomitant use of drugs at doses known to cause clinically relevant prolongation of QT/QTc interval.

NIH Site: clinicaltrials.gov/ct2/show/NCT04163900

Study ID: CRP19117

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A Phase 3, Open-Label, Randomized, Active-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Pemigatinib Versus Gemcitabine Plus Cisplatin Chemotherapy in First-Line Treatment of Participants With Unresectable or Metastatic Cholangiocarcinoma With FGFR2 Rearrangement (FIGHT-302)

Treatment Arm(s):

- A. Experimental: Pemigatinib
- B. Active Comparator: Gemcitabine + Cisplatin

Select Inclusion Criteria:

- Male and female participants at least 18 years of age at the time of signing the informed consent form (ICF); a legally minor participant from Japan needs written parental consent.
- Radiographically measurable or evaluable disease by CT or MRI per RECIST v1.1 criteria.
- Eastern Cooperative Oncology Group performance status 0 to 1.

Exclusion Criteria:

- Concurrent anticancer therapy, other than the therapies being tested in this study.
- Radiation therapy administered within 4 weeks of enrollment/randomization/first dose of study treatment.

NIH Site: clinicaltrials.gov/ct2/show/NCT03656536

Study ID: CRP18102

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CANCER

Hepatobiliary Malignancies

Safety and Efficacy of Pembrolizumab (MK-3475) Versus Placebo as Adjuvant Therapy in Participants With Hepatocellular Carcinoma (HCC) and Complete Radiological Response After Surgical Resection or Local Ablation (MK-3475-937 / KEY-NOTE-937)

Treatment Arm(s):

- A. Pembrolizumab
- B. Placebo

Select Inclusion Criteria:

- Has a diagnosis of HCC by radiological criteria and/or pathological confirmation.
- Has an eligibility scan confirming complete radiological response ≥ 4 weeks after complete surgical resection or local ablation.
- ECOG performance status of 0 within 7 days prior to Cycle 1, Day 1.
- Has a Child-Pugh class A liver score (5 to 6 points) within 7 days prior to Cycle 1, Day 1.
- Has alpha fetoprotein concentration lower than 400 ng/mL within 28 days prior to Cycle 1, Day 1.
- Has controlled hepatitis B (Hep B).
- Has recovered adequately from toxicity and/or complications from the local intervention (surgical resection or local ablation) prior to starting study treatment.

NIH Site: clinicaltrials.gov/ct2/show/NCT03867084

Study ID: CRP19025

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A Phase 2, Multicenter, Clinical Study to Evaluate the Safety and Efficacy of MK-1308A (Coformulated MK-1308/MK-3475) in Combination with Lenvatinib (E7080/MK-7902) in First-line Therapy of Participants with Advanced Hepatocellular Carcinoma

Primary Objective(s):

- A. To assess the safety and tolerability of study intervention with MK-1308A/lenvatinib.
- B. To evaluate the efficacy of MK-1308A/lenvatinib with respect to objective response rate (ORR) per Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 as assessed by blinded independent central review (BICR).

Select Inclusion Criteria:

- Has an HCC diagnosis confirmed by radiology, histology, or cytology (fibrolamellar and mixed hepatocellular/cholangiocarcinoma subtypes are not eligible).
- Has BCLC Stage C disease, or BCLC Stage B disease not amenable to locoregional therapy or refractory to locoregional therapy, and not amenable to a curative treatment approach.
- Has a Child-Pugh class A liver score within 7 days prior to first dose of study intervention.
- Has a predicted life expectancy of >3 months.
- Has at least 1 measurable HCC lesion based on RECIST 1.1, confirmed by BICR
- Is at least 18 years of age at the time of providing documented informed consent.

NIH Site: clinicaltrials.gov/ct2/show/NCT04740307

Study ID: CRP20102

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CANCER

HIV/AIDS Malignancies

Imiquimod, Fluorouracil, or Observation in Treating HIV-Positive Patients With High-Grade Anal Squamous Skin Lesions

Treatment Arm(s):

- A. Intra-anal Imiquimod
- B. Intra-anal fluorouracil
- C. Observation (no treatments)

Select Inclusion and Exclusion Criteria:

- HIV-positive
- Biopsy-proven HSIL
- Anal HSIL lesions are visible at study entry and no lesions are suspicious for invasive cancer
- Karnofsky performance status of $\geq 70\%$
- (CD)4 count ≥ 200 within 120 days prior to enrollment or plasma HIV-1 (RNA) < 200 copies/mL within 120 days prior to enrollment
- NO history of anal cancer
- NO Prior intra-anal use of topical 5-fluorouracil 5% or imiquimod 2.5%, 3.75% or 5% at any point, or use of perianal imiquimod 2.5%, 3.75% or 5% or topical 5-fluorouracil 5% within 6 months prior to enrollment
- NO Extensive concurrent perianal or lower vulvar HSIL or condyloma requiring a different treatment modality than the study treatment, or treatment that cannot be deferred in observation arm, per examining provider
- NO prior history of HPV Vaccination

NIH Site: clinicaltrials.gov/ct2/show/NCT02059499

Study ID: CRP17031

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**AMC-095, Nivolumab and Ipilimumab in Treating Patients With
Advanced HIV Associated Solid Tumors**

Treatment Arm(s):

INDUCTION PERIOD: Patients receive nivolumab IV over 60 minutes on days 1, 15, 29, and 43 (dose level -1 and 1) or days 1, 22, 43, and 64 (dose levels -2 and 2). Patients in dose levels -2 and 2 also receive ipilimumab IV over 90 minutes on days 1, 22, 43, and 64. Patients with an overall response of irSD, irPR, irCR, or unconfirmed irPD at the end of the Induction Period will enter the Maintenance Period.

MAINTENANCE PERIOD: Patients receive nivolumab IV over 60 minutes every 2 weeks for up to 42 infusions.

Select Inclusion and Exclusion Criteria:

- histologically confirmed solid tumor malignancy that is metastatic or unresectable and for which standard curative or palliative measures do not exist or are no longer effective; participants with uncontrolled Kaposi sarcoma are permitted
- HIV+
- Prior therapy for metastatic disease permitted; at least 4 weeks must have elapsed since prior chemotherapy or biological therapy, 6 weeks if the regimen included carmustine (BCNU) or mitomycin C; radiotherapy must be completed at least 28 days prior to registration
- ECOG \leq 1

NIH Site: clinicaltrials.gov/ct2/show/NCT02408861

Study ID: IRB15134

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CANCER

HIV/AIDS Malignancies

A Phase II Study of sEphB4-HSA in Kaposi Sarcoma

Treatment Arm(s):

- A. recombinant EphB4-HSA fusion protein (given IV)

Select Inclusion and Exclusion Criteria:

- Participants may be treatment naïve, refractory to or intolerant of one or more prior therapies, or treated with prior systemic treatment including but not limited to liposomal doxorubicin
- Participants must have biopsy-proven KS involving skin with or without visceral involvement
- If HIV-positive, any cluster of differentiation (CD)4 count will be allowed on study
- Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 or Karnofsky performance score (KPS) $\geq 60\%$
- Life expectancy of greater than 3 months
- If participant is HIV positive, participants must be on a stable antiretroviral regimen for at least 12 weeks prior to study enrollment
- There should be no evidence for improvement in KS in the 3 months prior to study enrollment, unless there is evidence for progression of KS in the 4 weeks immediately prior to study enrollment

NIH Site: clinicaltrials.gov/ct2/show/NCT02799485

Study ID: IRB16076

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A Pilot Study of Nelfinavir for the Treatment of Kaposi Sarcoma

Treatment Arm(s):

- A. Nelfinavir 1250 mg twice daily with escalation to 3125 mg twice daily

Select Inclusion and Exclusion Criteria:

- Biopsy-proven KS involving skin (with or without visceral involvement) without need for urgent cytotoxic therapy. There should be no evidence of improvement in KS in the 4 weeks immediately prior to study enrollment and treatment.
- Known HIV-1 infection status, as documented by any nationally approved, licensed HIV rapid test performed in conjunction with screening (or enzymelinked immunosorbent assay [ELISA] test kit), and confirmed by an approved test at each study site
- Participant may be either previously untreated for KS or refractory to or intolerant of any one or more prior KS therapies.
- ECOG performance status ≤ 2

NIH Site: clinicaltrials.gov/ct2/show/NCT03077451

Study ID: IRB16077

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CANCER

HIV/AIDS Malignancies

Phase I and Dose-Expansion Study of Ibrutinib and R-da-EPOCH for Front Line Treatment of AIDS-Related Lymphomas

Treatment Arm(s):

- A. R-da-EPOCH

Select Inclusion and Exclusion Criteria:

- Histologically documented CD20 positive or negative diffuse large B-cell lymphoma (DLBCL) Known HIV-1 infection status, as documented by any nationally approved, licensed HIV rapid test performed in conjunction with screening (or enzymelinked immunosorbent assay [ELISA] test kit), and confirmed by an approved test at each study site
- HIV-Positive
- Only participants whose lymphoma is untreated are allowed for the dose-finding portion
- ECOG performance status ≤ 2
- CD4 count ≥ 100
- No chemotherapy other than R-EPOCH or R-CHOP, or radiotherapy other than palliative within the last 4 weeks
- No Prior cytotoxic chemotherapy or radiotherapy for this lymphoma

NIH Site: clinicaltrials.gov/ct2/show/NCT03220022

Study ID: CRP17077

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Tissue Acquisition for Analysis of Prognostic Factors, Immunology, and Genetic Progression of HIV-1 Associated Malignancies

Primary Objective(s):

- A. To obtain high-quality, clinically annotated tissue from patients with human immunodeficiency virus (HIV)-1 malignancy.
- B. To study clinical, genetic, and immunologic parameters that have prognostic significance and/or are involved in the initiation and progression of HIV-1 malignancies, including complete genomic sequence determination of HIV-associated diffuse large B-cell lymphomas, lung cancer, anal cancer, and cervical cancer.

Select Inclusion and Exclusion Criteria:

- Participants must have a diagnosis of a malignancy or clinical findings suggestive of a possible HIV-associated malignancy of one of three types:
 - Diffuse large B-cell lymphoma
 - Non-small cell lung malignancy
- The presence of any of the following conditions will exclude a participant from study enrollment:
 - Absence of sufficient diagnostic tumor-biopsy tissue material to meet the protocol requirements for baseline specimen submission (minimum specimen size of 10 x 10 x 2 mm); repeat tumor biopsy will not be performed solely to meet the protocol specimen-collection requirements
 - Participants whose biopsies, for the purpose of this protocol, show a diagnosis of anal intraepithelial neoplasia or cervical intraepithelial neoplasia

NIH Site: clinicaltrials.gov/ct2/show/NCT01567722

Study ID: IRB12062

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CANCER

HIV/AIDS Malignancies

Anal Cancer Prevention

ANCHOR Study: Topical or Ablative Treatment in Preventing Anal Cancer in Patients With HIV and Anal High-Grade Squamous Intraepithelial Lesions

Treatment Arm(s):

- A. Patients are directed to receive either topical or ablative treatment at the discretion of the clinician including: imiquimod, fluorouracil or trichloroacetic acid, infrared coagulation, hyfrecation/electrocautery, or laser. Patients may also undergo excision under anesthesia
- B. Active monitoring

Select Inclusion and Exclusion Criteria:

- HIV-1 infection
- No HSIL treatments in past 6 months
- No history of anal cancer or signs of anal cancer at baseline, and no history of penile, vulvar, vaginal or cervical cancer
- Biopsy-proven HSIL at baseline
- At least one focus of HSIL must be identified that is not within a condyloma that may be treated after enrollment into the study

NIH Site: clinicaltrials.gov/ct2/show/NCT02135419

Study ID: IRB14114

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A Phase 2 Open-label Study of Brentuximab Vedotin in Front-line Therapy of Hodgkin Lymphoma (HL) an dCD30-expressing Peripheral T-cell Lymphoma (PTCL) in Older Patients or Patients With Significant Comorbidities Ineligible for Standard Chemotherapy

Treatment Arm(s):

- A. Brentuximab Vedotin in HL Patients
- B. Brentuximab Vedotin + Dacarbazine in HL Patients
- C. Brentuximab Vedotin + Bendamustine in HL Patients
- D. Brentuximab Vedotin + Nivolumab in HL Patients
- E. Brentuximab Vedotin in HL Patients
- F. Brentuximab Vedotin in HL Patients

Select Inclusion Criteria:

- Parts A, B, C, and D: 60 years of age or older
- Treatment-naive patients with histopathological diagnosis of classical Hodgkin lymphoma (Parts A, B, C, D, and E)
- Measurable disease of at least 1.5 cm as documented by radiographic technique
- Eastern Cooperative Oncology Group (ECOG) performance status less than or equal to 3 (Parts, A, B, C, E, and F) or less than or equal to 2 (Part D)

Exclusion Criteria:

- Symptomatic neurologic disease compromising IADLs or requiring medication

NIH Site: clinicaltrials.gov/ct2/show/NCT01716806

Study ID: CRP20079

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CANCER

Lymphoma

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Tafasitamab Plus Lenalidomide in Addition to Rituximab Versus Lenalidomide in Addition to Rituximab in Patients With Relapsed/Refractory (R/R) Follicular Lymphoma Grade 1 to 3a or R/R Marginal Zone Lymphoma

Treatment Arm(s):

- A. tafasitamab + rituximab + lenalidomide
- B. placebo + rituximab + lenalidomide

Select Inclusion Criteria:

- Histologically confirmed Grade 1, 2, or 3a FL or nodal MZL, splenic MZL, or extra nodal MZL
- In the opinion of the investigator, be able and willing to receive adequate mandatory prophylaxis and/or therapy for thromboembolic events (eg, aspirin 70-325 mg daily or low-molecular-weight heparin)
- ECOG performance status of 0 to 2

Exclusion Criteria:

- Any histology other than FL and MZL or clinical evidence of transformed lymphoma

NIH Site: clinicaltrials.gov/ct2/show/NCT04680052

Study ID: CRP21001

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Post-Authorization Long-Term Safety Study of LUTATHERA (SALUS)

Treatment Arm(s):

- A. Lutathera

Select Inclusion Criteria:

- patients with unresectable or metastatic, well-differentiated, somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours treated with LUTATHERA

Select Exclusion Criteria:

- hypersensitivity to LUTATHERA (active substance or any of the excipients)
- pregnancy (established, suspected, or when not excluded)
- kidney failure with creatinine clearance < 30 mL/min

NIH Site: clinicaltrials.gov/ct2/show/NCT03691064

Study ID: CRP18067

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Randomized, Double-Blinded Phase III Study of Cabozantinib Versus Placebo in Patients With Advanced Neuroendocrine Tumors After Progression on Prior Therapy (CABINET)

Treatment Arm(s):

- A. Experimental: Arm I (cabozantinib S-malate)
- B. Placebo Comparator: Arm II (placebo)

Select Inclusion Criteria:

- Histologic Documentation: Well- or moderately-differentiated neuroendocrine tumors of pancreatic and non-pancreatic (i.e. carcinoid) origin by local pathology
- Tumor Site: Histological documentation of neuroendocrine tumor of pancreatic, gastrointestinal (GI), lung, or unknown primary site; GI, lung, and unknown primary NETs will enroll in the carcinoid tumor cohort of the study
- Patients must have measurable disease per RECIST 1.1 by computer tomography (CT) scan or magnetic resonance imaging (MRI)
- Prior treatment with cabozantinib is not allowed
- No known history of congenital long QT syndrome
- Women of childbearing potential must have a negative pregnancy test done \leq 14 days prior to registration

NIH Site: clinicaltrials.gov/ct2/show/NCT03375320

Study ID: CRP20035

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Alternating neoadjuvant Gemcitabine-Nab-Paclitaxel and na1-IRI with 5-Fluorouracil and folinic acid (Leucovorin) regimens in resectable and borderline resectable pancreatic cancer, A Pilot Study

Only borderline resectable pancreatic cancer is open at this time

Primary Objective(s):

Safety, tolerability, and feasibility of gemcitabine-nab paclitaxel alternating with na1-IRI/5FU/leucovorin (NAPOLI) in borderline resectable pancreatic cancer

Select Inclusion Criteria:

- Pathologically proven pancreatic cancer
- Borderline resectable pancreatic cancer per NCCN guidelines
- Age ≥ 18
- ECOG PS 0/1
- Adequate hematologic/hepatic and renal function by standard parameters

Select Exclusion Criteria:

- Prior definitive resection of pancreatic cancer
- Prior chemotherapy or radiation therapy for pancreatic cancer
- Neuropathy $>$ grade 1
- Any other basis for study exclusion per investigator discretion
- Unable or unwilling to provide written signed informed consent

NIH Site: clinicaltrials.gov/ct2/show/NCT03703063

Study ID: CRP17118

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CANCER

Pancreas

Gemcitabine and nab-paclitaxel in pancreatic adenocarcinoma with positive peritoneal cytology as a sole metastatic site

Primary Objective(s):

- A. Cytological Conversion

Select Inclusion Criteria:

- Pathologically proven pancreatic cancer
- Localized with positive peritoneal cytology as a sole metastatic site
- Age >18
- ECOG PS 0/1
- Signed informed consent

NIH Site: clinicaltrials.gov/ct2/show/NCT03703089

Study ID: CRP17130

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Pivotal, Randomized, Open-label Study of Tumor Treating Fields (TTFields, 150kHz) Concomitant With Gemcitabine and Nab-paclitaxel for Front-line Treatment of Locally-advanced Pancreatic Adenocarcinoma

Treatment Arm(s):

- A. NovoTTF-100L(P)
- B. Best standard of care

Select Inclusion Criteria:

- 18 years of age and older
- Life expectancy of ≥ 3 months
- Histological/cytological diagnosis of de novo adenocarcinoma of the pancreas
- Unresectable, locally advanced stage disease
- ECOG score 0-2
- Amenable and assigned by the investigator to receive therapy with gemcitabine and nab-paclitaxel
- Able to operate the NovoTTF-100L(P) System independently or with the help of a caregiver
- NO Prior palliative treatment (e.g. surgery, radiation) to the tumor

NIH Site: clinicaltrials.gov/ct2/show/NCT03377491

Study ID: CRP18024

PI: Vincent Picozzi, MD / CRC: Anas Najjar / (206) 287-6271

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CANCER

Pancreas

Distal Pancreatectomy, Minimally Invasive Or Open, For Malignancy (DIPLOMA): A Randomized Controlled, Multicenter, Non-Inferiority Trial

Treatment Arm(s):

- A. MIDP
- B. ODP

Select Inclusion Criteria:

- ≥ 18 years
- Elective indication for distal pancreatectomy for proven or suspected PDAC
- Upfront (without induction / down-sizing radio- or chemotherapy) resectable PDAC in the pancreatic body or tail
- The tumor can be radically resected via both minimally invasive or open surgery according to the local treating team

Study ID: CRP18049

PI: Scott Helton, MD / CRC: Anas Najjar / (206) 287-6271

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Locally advanced, unresectable

A Phase 3, Randomized, Double-Blind Study of Pamrevlumab or Placebo in combination with Gemcitabine Plus Nab-paclitaxel as Neoadjuvant Treatment in Patients with Locally Advanced, Unresectable Pancreatic Cancer

Treatment Arm(s):

- A. Pamrevlumab + G/NP
- B. Placebo + G/NP

Select Inclusion Criteria:

- Reduction in CA19-9 level $\geq 50\%$
- FDG-PET SUVmax decrease by $\geq 30\%$ at EOT when compared to baseline
- Partial response [PR], complete response [CR], or stable disease [SD] per RECIST
- 1.1 at EOT
- Meet the definition of resectable or borderline resectable per NCCN®

NIH Site: clinicaltrials.gov/ct2/show/NCT03941093

Study ID: CRP18119

PI: Vincent Picozzi, MD / CRC: Anas Najjar / (206) 287-6271

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CANCER

Pancreas

Precision Promise Platform Trial For Metastatic Pancreatic Cancer

Treatment Arm(s):

- A. Active Comparator: Enzalutamide
- B. Experimental: I-131-1095 in combination with enzalutamide

Select Inclusion and Exclusion Criteria:

- Age \geq 18 years
- Histologically or cytologically confirmed metastatic pancreatic adenocarcinoma
- Eastern Cooperative Oncology Group (ECOG) performance status of 0-1
- Adequate organ function (lab results must be obtained within the 28-day window prior to randomization)
- Consent to provide protocol-mandated tissue and blood samples for diagnostic and research purposes
- Received any therapy within 28 days (or 5 half-lives, whichever is shorter,) prior to randomization
- History of allergy or hypersensitivity to any of the study treatments or any of their excipients
- Known history of hepatitis B, HIV or active hepatitis C infection
- Receiving immunosuppressive or myelosuppressive medications that would, in the opinion of the Investigator, increase the risk of serious neutropenic complications

Study ID: CRP19086

PI: Vincent Picozzi, MD / CRC: Anas Najjar / (206) 287-6271

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Comparing the Clinical Impact of Pancreatic Cyst Surveillance Programs

Treatment Arm(s):

- A. Experimental: Arm I (low intensity surveillance)
- B. Experimental: Arm II (high intensity surveillance)

Select Inclusion Criteria:

- 50 Years to 75 Years
- Patients must have an Eastern Cooperative Oncology Group (ECOG) performance status 0-1
- Patient must have received a computed tomography (CT) or magnetic resonance imaging (MRI) within 3 months of registration that revealed a newly identified ≥ 1 cm pancreatic cyst
- Patient must not have other asymptomatic pancreatic cystic lesion with zero/low malignancy potential (pancreatic pseudocyst, classic serous cystic lesion) on index CT or MRI
- Patient must not have a family history of pancreatic adenocarcinoma in 1 or more first degree relatives
- Patient must not have pancreatic cyst morphology that would prompt immediate surgical consideration (enhancing mural nodule, solid component in cyst, pancreatic duct > 10 mm, cyst causing obstructive jaundice)

NIH Site: clinicaltrials.gov/ct2/show/NCT04239573

Study ID: CRP20053

PI: Joanna Law, MD / CRC: Karolina Rauch / (206) 287-6279

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CANCER

Prostate

Phase III IGRT and SBRT vs IGRT and Hypofractionated IMRT for Localized Intermediate Risk Prostate Cancer

Treatment Arm(s):

- A. Intensity-Modulated Radiation Therapy (IMRT):
Patients undergo Intensity-Modulated Radiation Therapy (IMRT) once daily 5 fractions per week for 28 fractions over less than 32 business days.
- B. Stereotactic Body Radiation Therapy (SBRT):
Patients undergo Stereotactic Body Radiation Therapy (SBRT) at least every other day for 2-3 fractions per week for 5 fractions over less than 12 business days.

Select Inclusion and Exclusion Criteria:

- History and physical including a digital rectal exam 60 days prior to registration
- Eastern Cooperative Oncology Group (ECOG) performance status 0-1 60 days prior to registration
- MRI of the prostate and pelvis (compliant with PIRADSV2.1 guidelines) within 1 year prior to registration
- Prior or current invasive malignancy with current evidence of active disease within the past 2 years
- Prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields

NIH Site: clinicaltrials.gov/ct2/show/NCT03367702

Study ID: CRP20022

PI: Huong Pham, MD / CRC: Rachel Dowty / (206) 287-6275

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A Multicenter, Randomized, Controlled Phase 2 Study: Efficacy and Safety of I-131-1095 Radiotherapy in Combination With Enzalutamide in Metastatic Castration-resistant Prostate Cancer (mCRPC) Patients Who Are 18F-DCFPyL Prostate-specific Membrane Antigen (PSMA)-Avid, Chemotherapy-naive, and Progressed on Abiraterone

Treatment Arm(s):

- A. Active Comparator: Enzalutamide
- B. Experimental: I-131-1095 in combination with enzalutamide

Select Inclusion and Exclusion Criteria:

- Male \geq 18 years of age
- Histologically or cytologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation or small cell features at initial diagnosis
- Castration-resistant prostate cancer, with serum testosterone \leq 50 ng/dL at Screening
- Radiographic evidence of metastatic disease prior to Randomization or up to 21 days prior to Screening
- Received any anti-tumor therapy within 4 weeks of Randomization, with the exception of abiraterone, GnRH therapy and non-radioactive bone-targeted agents
- Active malignancy other than prostate cancer, with the exception of curatively treated non-melanoma skin cancer, carcinoma in situ, or non-muscle invasive bladder/urothelial cancer

NIH Site: clinicaltrials.gov/ct2/show/NCT03939689

Study ID: CRP19092

PI: John Paul Flores, MD / CRC: Rachel Dowty / (206) 287-6275

Pager: (206) 797-1888 / Rachel.Dowty@VirginiaMason.org



CANCER

Prostate

Does the Use of a Post-Operative Pedometer Affect Rate of Return of Bowel Function and Narcotic Use Following Radical Prostatectomy?

Treatment Arm(s):

This study will evaluate whether use of pedometer with progressing step-count goals following radical prostatectomy decreases post-operative narcotic use and decreases the time before return of bowel function.

Select Inclusion and Exclusion Criteria:

- Male between 18 and 75 years of age undergoing robot-assisted laparoscopic radical prostatectomy for prostate cancer at Virginia Mason Medical Center
- Long-term, opioid use, defined by the CDC as use of opioids on most days for more than 3 months
- History of inflammatory bowel disease
- Prior abdominopelvic radiation
- Concurrent surgery during radical prostatectomy
- Inability to ambulate
- Gastroparesis or other baseline bowel dysmotility issues
- Inability or unwillingness of subject or legal guardian/representative to give written informed consent

Study ID: CRP19098

PI: John Corman, MD / CRC: Marina Jovic / (206) 287-6282

Marina.Jovic@VirginiaMason.org



A Phase 1a/b Dose-Escalation Study Followed by Expansion Cohorts of NGM120, a GFRAL Antagonist Monoclonal Antibody Blocking GDF15 Signaling, in Subjects With Advanced Solid Tumors and Pancreatic Cancer Using Combination Therapy

Treatment Arm(s):

- A. NGM120 Subcutaneous Injection Doses 1-6
- B. Placebo

Select Inclusion and Exclusion Criteria:

- Have histologically confirmed advanced or metastatic castration-resistant prostate cancer, bladder cancer, melanoma, non-small cell lung cancer, pancreatic cancer, colorectal cancer, gastric cancer, esophageal cancer, ovarian cancer, and head neck squamous cell carcinoma.
- Have not received any approved chemotherapy, except in the adjuvant setting.
- Subject was using immunosuppressive medications within 14 days before Screening with the exception of topical (intranasal, inhaled, and local injection), systemic (prednisone equivalent 10 mg/day or less), or as needed for hypersensitivity reactions such as computed tomography (CT) scan premedication.
- Subject has active infections or other serious underlying significant medical illness, abnormal and clinically significant laboratory findings or psychiatric illness/social situation.

NIH Site: clinicaltrials.gov/ct2/show/NCT04068896

Study ID: CRP19071

PI: Vincent Picozzi, MD / CRC: Anas Najjar / (206) 287-6271

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CANCER

Solid Tumors

Evaluating the use of a Smartphone Application and Biosensor by Cancer Patients Undergoing Systemic Treatments

Primary Objective(s):

- Feasibility of the study recruitment protocol measured by the number of patients screened, the proportion of patients who are eligible, and percent age of eligible patients who consent to participate each month.
- Feasibility of the onboarding protocol as measured by the percentage of consenting patients with a successfully activated APP and Sensor and the percentage of consenting patients who successfully complete the APP electronic patient-reported outcomes (ePRO) survey and synchronize the Sensor in the 24-hours before treatment initiation.

Select Inclusion and Exclusion Criteria:

- 18–80 years of age
- Have a biopsy-proven current diagnosis of cancer
- Planning to receive but have not yet begun IV cancer therapy and/or are within 3 days of starting oral cancer systemic therapy as an initial or a new line of treatment for their current disease
- Have a personal iPhone or Android device with cellular service, Bluetooth®-data plan and/or WiFi
- Able to wear the selected Sensor daily and as advised by the manufacturer's device instruction manual
- Able to provide informed consent, understand and provide information for study forms and in APP ePRO survey and questionnaires in English
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0–2 at enrollment

Study ID: CRP21027

PI: Mark Beiter, MD / CRC: Anas Najjar / (206) 287-6271

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A Phase I/II Study of MCLA-128, a full length IgG1 Bispecific Antibody Targeting HER2 and HER3, in Patients with Solid Tumors

Primary Objective(s):

- Feasibility of the study recruitment protocol measured by the number of patients screened, the proportion of patients who are eligible, and percent age of eligible patients who consent to participate each month.
- Feasibility of the onboarding protocol as measured by the percentage of consenting patients with a successfully activated APP and Sensor and the percentage of consenting patients who successfully complete the APP electronic patient-reported outcomes (ePRO) survey and synchronize the Sensor in the 24-hours before treatment initiation.

Select Inclusion and Exclusion Criteria:

- 18–80 years of age
- Have a biopsy-proven current diagnosis of cancer
- Planning to receive but have not yet begun IV cancer therapy and/or are within 3 days of starting oral cancer systemic therapy as an initial or a new line of treatment for their current disease
- Have a personal iPhone or Android device with cellular service, Bluetooth®-data plan and/or WiFi
- Able to wear the selected Sensor daily and as advised by the manufacturer's device instruction manual
- Able to provide informed consent, understand and provide information for study forms and in APP ePRO survey and questionnaires in English
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0–2 at enrollment

NIH Site: clinicaltrials.gov/ct2/show/NCT02912949

Study ID: CRP20087

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CARDIOLOGY/CARDIAC SURGERY

Coronary Artery Disease

ECLIPSE: Evaluation Of Treatment Strategies For Severe Calcific Coronary Arteries: Orbital Atherectomy Vs. Conventional Angioplasty Technique Prior To Implantation Of Drug-Eluting Stents

Treatment Arm(s):

- A. Orbital Atherectomy (OA)
- B. Conventional Balloon Angioplasty

Select Inclusion Criteria:

- Stable ischemic heart disease or
- acute coronary syndrome (NSTEMI or unstable angina), or
- stabilized recent STEMI (>48 hours prior to randomization procedure)

Select Exclusion Criteria:

- Any prior PCI in the target vessel or its branches 12 months prior to randomization.
- Subject has undergone a PCI procedure that is unsuccessful or with complications within 30 days prior to randomization, including during the randomization procedure.
- Any cardiac intervention or surgery planned within 12 months post randomization procedure aside from a potential planned staged PCI as part of the randomized treatment strategy.
- Subject has received a heart transplant.
- Evidence of heart failure

NIH Site: clinicaltrials.gov/ct2/show/NCT03108456

Study ID: CRP18090

PI: Drew Baldwin, MD / CRC: Kate Duran / (206) 287-6268

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Irrigated Radio Frequency Ablation to Terminate Non-Paroxysmal Atrial Fibrillation (Terminate AF Study)

Treatment Arm(s):

- A. Experimental: Primary Cohort
Patients with a history of persistent atrial fibrillation and long-standing persistent atrial fibrillation (non-paroxysmal atrial fibrillation) who are undergoing concomitant cardiac surgery

Select Inclusion Criteria:

- History of non-paroxysmal AF (persistent or longstanding persistent)
- Able to take the anticoagulant warfarin or novel oral anticoagulants (NOAC)

Select Exclusion Criteria:

- Wolff-Parkinson-White syndrome
- NYHA Class = IV
- Left Ventricular Ejection Fraction $\leq 30\%$
- Left atrial diameter > 6.0 cm
- Predicted risk of operative mortality $>10\%$ as assessed by STS Risk Calculator
- Current diagnosis of active systemic infection

NIH Site: clinicaltrials.gov/ct2/show/NCT03546374

Study ID:CRP20088

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DIABETES

TrialNet Pathway to Prevention Study

Type 1 Diabetes Risk Screening for relatives

Relatives of people with T1D are 15 times more likely to develop the disease than the general population. TrialNet offers screening to family members, free of charge, for autoantibodies that can indicate risk of developing T1D years before symptoms appear. Anyone shown to be at increased risk can be monitored and may be eligible for a prevention trial.

Inclusion Criteria:

- **First-degree relatives:** Parents, siblings, and children of T1D patients are eligible to screen if they are age 2.5 – 45 years.
- **Second-degree relatives:** Cousins, nieces, nephews, aunts, uncles, grandchildren, and half-siblings of T1D patients are eligible to screen if they are 2.5 – 20 years.

Please refer your patients to www.TrialNet.org to order test kits, mailed to their home, free of charge.

NIH Site: clinicaltrials.gov/ct2/show/NCT00097292

Study ID: 10102

PI: Carla Greenbaum, MD

1 (800) 888-4187 / Diabetes@BenaroyaResearch.org



DREAMT Study - Early Markers of Disease and Response to Therapy

DREAMT study for newly diagnosed type 1 diabetes

In earlier studies, abatacept was shown to slow down beta cell destruction and preserve insulin secretion in people after diagnosis of type 1 diabetes. Abatacept seemed to work better in some people than others. This study seeks to identify markers that predict how effective abatacept will be in individuals newly diagnosed with type 1 diabetes.

Select Inclusion Criteria:

- Type 1 diabetes diagnosis within the last six months
- Age 6-45 years

NIH Site: clinicaltrials.gov/ct2/show/NCT04118153

Study ID: 19091

PI: Carla Greenbaum, MD

1 (800) 888-4187 / Diabetes@BenaroyaResearch.org



DIABETES

Diabetes Mellitus, Type 1

Diabetes Translational Research Project

BRIDgE study – Diabetes Translational Research Project

We are inviting patients with type 1 diabetes to participate in a research study to help us improve our understanding of diabetes and immune-mediated diseases. The study consists of a computer registry of patients' contact, research, and health information; and a sample repository of blood and other biologic samples for current and future use in research at Benaroya Research Institute. The samples will be used for many different studies at Benaroya Research Institute.

Select Inclusion Criteria:

- Type 1 diabetes diagnosis
- Age 55 and under
- Live in the greater Seattle area

Study ID: 10024

PI: Carla Greenbaum, MD

1 (800) 888 – 4187 / diabetes@benaroyaresearch.org



TOPPLE T1D study for new-onset type 1 diabetes

This study is testing the safety of a new treatment, NNC0361-0041, in adults with T1D. The treatment is a plasmid vector designed to transfer DNA into cells, where it can communicate with the immune system.

Earlier studies show this treatment might retrain the immune system to stop its attack on insulin-producing beta cells.

While plasmids are small circular pieces of DNA, they do not change your DNA. They are currently being studied in many clinical trials for other conditions.

Select Inclusion Criteria:

- **T1D diagnosis within past four years.**
- **Age 18 through 45 years**

NIH Site: clinicaltrials.gov/ct2/show/NCT04279613

Study ID: 18044

PI: Carla Greenbaum, MD

1 (800) 888 – 4187 / diabetes@benaroyaresearch.org



DIGESTIVE DISEASES

Endoscopy

Pancreatitis

Stent vs. Indomethacin for Preventing Post-ERCP Pancreatitis

Treatment Arm(s):

- A. Indomethacin alone
- B. Indomethacin + pancreatic stent

Select Inclusion Criteria:

Clinical suspicion of or known sphincter of Oddi dysfunction

- History of post-ERCP pancreatitis
- Pancreatic sphincterotomy
- Pre-cut (access) sphincterotomy (freehand pre-cut and septotomy)
- Difficult cannulation:
- Short-duration (≤ 1 min) balloon dilation of an intact biliary sphincter.

Or has at least 2 of the following:

- Age < 50 years old & female gender
- History of recurrent pancreatitis (at least 2 episodes)
- ≥ 3 pancreatic injections
- Pancreatic acinarization
- Pancreatic brush cytology

NIH Site: clinicaltrials.gov/ct2/show/NCT02476279

Study ID: CRP18061

PI: Andrew Ross, MD / CRC: Audrey Merz / 206-341-1457

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*Recurrent Pancreatitis***SpHincterotomy for Acute Recurrent Pancreatitis (SHARP)***Treatment Arm(s):*

- A. EUS + Sham
- B. EUS + ERCP with miES

Select Inclusion Criteria:

- >18 years
- Two or more episodes of acute pancreatitis, with each episode meeting two of the following three criteria:
 - abdominal pain consistent with acute pancreatitis (acute onset of a persistent, severe, epigastric pain often radiating to the back)
 - serum lipase activity (or amylase activity) at least three times greater than the upper limit of normal
 - characteristic findings of acute pancreatitis on CECT, MRI or transabdominal ultrasonography
- At least one episode of acute pancreatitis within 24 months of enrollment
- Pancreas divisum confirmed by prior MRCP that is reviewed by an abdominal radiologist at the recruiting site.
- By physician assessment, there is no certain explanation for recurrent acute pancreatitis.

NIH Site: clinicaltrials.gov/ct2/show/NCT03609944

Study ID: CRP18078

PI: Andrew Ross, MD / CRC: Cheryl Shaw / (206) 341-1786

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DIGESTIVE DISEASES

General Surgery

Diverticulitis

Institutional Database for medical and surgical management of diverticulitis

Treatment Arm(s):

- A. Partial Colectomy
- B. Medical Management

Select Inclusion Criteria:

- Adults ≥ 18 years
- At least one episode of diverticulitis confirmed by CT scan in last 5 years and a colonoscopy to rule out or screen for other colon pathology concordant with screening guidelines; AND A. History of recurrent uncomplicated diverticulitis without current symptoms (AUD in remission) over the prior 5 years; OR B. Persistent signs, symptoms, and concerns related to diverticular disease ≥ 3 months after recovery from an episode of AUD (e.g., excluding irritable bowel syndrome and other conditions in coordination with gastroenterologist)

Select Inclusion Criteria:

- Previous operation for diverticulitis
- Current diagnosis or previous endoscopic or surgical interventions for bleeding, fistula, stricture related to diverticular disease
- Actively undergoing chemotherapy or radiation for malignancy
- Immunodeficiency (e.g., absolute neutrophil count $< 500/\text{mm}^3$, chronic immunosuppressive drugs (e.g., oral corticosteroids, anti-TNF agents), or known AIDS [i.e., recent CD4 count < 200] assessed by patient history)

NIH Site: clinicaltrials.gov/ct2/show/NCT04095663

Study ID: CRP19057

PI: Val Simianu, MD / CRC: Audrey Merz / 206-341-1457

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*Crohn's Disease***A Phase 3, Multicenter, Randomized, Efficacy Assessor-Blinded Study of Risankizumab Compared to Ustekinumab for the Treatment of Adult Subjects With Moderate to Severe Crohn's Disease Who Have Failed Anti-TNF Therapy***Treatment Arm(s):*

- A. Experimental: Risankizumab Dose A Followed by Dose B
- B. Experimental: Risankizumab Dose A Followed by Dose C
- C. Active Comparator: Ustekinumab

Select Inclusion Criteria:

- 18 Years to 80 Years
- Confirmed diagnosis of Crohn's disease (CD) for at least 3 months prior to Baseline.
- Crohn's disease activity index (CDAI) score 220 - 450 at Baseline.
- Demonstrated intolerance or inadequate response to one or more anti-tumor necrosis factor (TNF) therapies.

Select Exclusion Criteria:

- Current diagnosis of ulcerative colitis or indeterminate colitis.
- Prior exposure to p19 and/or p40 inhibitors (e.g., risankizumab and ustekinumab).

NIH Site: clinicaltrials.gov/ct2/show/NCT04524611

Study ID: CRP20081

PI: Timothy Zisman, MD / CRC: Katie Gelinias / (206) 341-1992

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DIGESTIVE DISEASES

IBD

Crohn's Disease

A Phase-III, Randomized, Double-blind, Parallel-group, Placebo-controlled, International, Multicentre Study to Assess Efficacy and Safety of Cx601, Adult Allogeneic Expanded Adipose-derived Stem Cells (eASC) for the Treatment of Complex Perianal Fistula(s) in Patients With Crohn's Disease Over a Period of 24 Weeks and a Follow-up Period up to 52 Weeks

Treatment Arm(s):

- A. Cx601 eASCs 120 million cells (5 million cells per milliliter [mL]) will be administered once by intralesional injection
- B. CX601 placebo-matching eASCs cells will be administered once by intralesional administration

Select Inclusion Criteria:

- Participants of either gender greater than or equal to (\geq) 18 years and less than or equal to (\leq) 75 years of age
- Participants with CD diagnosed at least 6 months prior to Screening visit in accordance with accepted clinical, endoscopic, histological and/or radiological criteria

Select Exclusion Criteria:

- Concomitant rectovaginal or rectovesical fistula(s)
- Severe rectal and/or anal stenosis and/or severe proctitis (defined as the presence of large >0.5 cm ulcers in the rectum) that make impossible to follow the surgery procedure manual
- Any major surgery of the GI tract (including one or more segments of the colon or terminal ileum) within 6 months prior the screening or any minor surgery of the GI tract within 3 months prior to screening

NIH Site: clinicaltrials.gov/ct2/show/NCT03279081

Study ID: CRP18046

PI: Timothy Zisman, MD / **CRC:** Cheryl Shaw / (206) 341-1786

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*Crohn's Disease***A Maintenance and Long-Term Extension Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects With Crohn's Disease Who Completed the Studies M14-431 or M14-433***Treatment Arm(s):*

Group A arm A: Upadacitinib dose B

Group A arm B: Upadacitinib dose C

Group A arm C: Placebo for Upadacitinib

Group B arm A: Long term extension, Upadacitinib dose B

Group B arm B: Long term extension, Upadacitinib dose C

Group B arm C: Long term extension, Upadacitinib

Select Inclusion Criteria:

- For Substudy 1: Participant who receive double-blind treatment in Study M14-431 or Study M14-433 and achieve clinical response. Participant completes study procedures in the parent study.
- For Substudy 2: Participant completes Substudy 1. Participant who receive open-label upadacitinib Dose B in Study M14-431 and achieve clinical response. Participant completes study procedures in the parent study/substudy.

NIH Site: clinicaltrials.gov/ct2/show/NCT03345823

Study ID: CRP17098

PI: Timothy Zisman, MD / CRC: Cheryl Shaw / (206) 341-1786

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DIGESTIVE DISEASES

IBD

Ulcerative Colitis

A Randomized, Double-Blind, Placebo-Controlled, 52-Week Study to Assess the Efficacy and Safety of Etrasimod in Subjects With Moderately Active Ulcerative Colitis

Treatment Arm(s):

- A. Experimental: Etrasimod 2 mg
- B. Placebo Comparator: Placebo

Select Inclusion Criteria:

- 18 Years to 80 Years
- Diagnosed with Ulcerative Colitis (UC) \geq 3 months prior to screening
- Active UC confirmed by endoscopy
Received a surveillance colonoscopy within 12 months before baseline

Select Exclusion Criteria:

- Severe extensive colitis
- Diagnosis of Crohn's disease or indeterminate colitis or the presence or history of a fistula consistent with Crohn's disease
- Hospitalization for exacerbation of UC requiring intravenous steroids within 12 weeks prior to or after screening

NIH Site: clinicaltrials.gov/ct2/show/NCT04607837

Study ID: CRP20094

PI: Timothy Zisman, MD / **CRC:** Katie Gelinias / (206) 341-1992

Pager: (206) 797-0393 / Katharyn.Gelinias@VirginiaMason.org

*Ulcerative Colitis***An Open-Label Extension Study of Etrasimod in Subjects With Moderately to Severely Active Ulcerative Colitis***Treatment Arm(s):*

- A. Etrasimod 2 mg

Select Inclusion Criteria:

Must have met the eligibility criteria and have been enrolled in one of the two parent studies (APD334-301 or APD334-302) and also meet the following additional criteria:

- Participants previously enrolled in Study APD334-301 must have completed the Week 12 visit and have been assessed to have active UC that had deteriorated from baseline or completed the Week 52 visit
- Participants previously enrolled in APD334 302 must have completed the Week 12 visit

Select Exclusion Criteria:

- If Investigator considers the participant to be unsuitable for any reason to participate in the Open-Label Extension study
- Experienced an adverse event that led to discontinuation from one of the parent studies

NIH Site: clinicaltrials.gov/ct2/show/NCT03950232

Study ID: CRP19017

PI: Timothy Zisman, MD / CRC: Kate Beck / (206) 341-1786

Pager: (206) 341-1465 / Kate.Beck@VirginiaMason.org



DIGESTIVE DISEASES

IBD

Ulcerative Colitis

A Study to Assess the Efficacy and Safety of Risankizumab in Subjects With Ulcerative Colitis Who Responded to Induction Treatment in M16-067 or M16-065

Treatment Arm(s):

- A. Risankizumab
- B. Placebo

Select Inclusion Criteria:

- Subjects who have completed Study M16-065 or Study M16-067 and have achieved clinical response

Select Exclusion Criteria:

- Subjects who have a known hypersensitivity to risankizumab or the excipients of any of the study drugs or the ingredients of chinese hamster ovary (CHO) or had an adverse event (AE) during Studies M16-065 or M16-067 that in the Investigator's judgment makes the subject unsuitable for this study

NIH Site: clinicaltrials.gov/ct2/show/NCT03398135

Study ID: CRP18016

PI: Timothy Zisman, MD / CRC: Cheryl Shaw / (206) 341-1786

Pager: (206) 989-9308 / Cheryl.Shaw@VirginiaMason.org

*Ulcerative Colitis***A Multicenter, Randomized, Double-Blind, Placebo Controlled Induction Study to Evaluate the Efficacy and Safety of Risankizumab in Subjects With Moderately to Severely Active Ulcerative Colitis Who Have Failed Prior Biologic Therapy***Treatment Arm(s):*

- A. Risankizumab
- B. Placebo

Select Inclusion Criteria:

- Male or female aged ≥ 18 to ≤ 80 years at the Baseline Visit. Where locally permissible, subjects 16 to < 18 years of age who meet the definition of Tanner stage 5 for development at the Baseline Visit
- Confirmed diagnosis of ulcerative colitis (UC) for at least 3 months prior to Baseline.
- Active UC as assessed by adapted Mayo Score
- Demonstrated intolerance or inadequate response to one or more biologic therapies
- Females must be postmenopausal for more than 2 years or surgically sterile or practicing specific forms of birth control.

NIH Site: clinicaltrials.gov/ct2/show/NCT03398148

Study ID: CRP18017

PI: Timothy Zisman, MD / CRC: Cheryl Shaw / (206) 341-1786

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INFECTIOUS DISEASES

COVID-19

COVID-19 Post-hospital Thrombosis Prevention Trial: An Adaptive, Multicenter, Prospective, Randomized Platform Trial Evaluating the Efficacy and Safety of Antithrombotic Strategies in Patients With COVID-19 Following Hospital Discharge

Treatment Arm(s):

In this study, we aim to prospectively quantify the incidence and additional risk factors of VTE in our ALS population. Our secondary objective is to characterize the accuracy of D-dimer testing for exclusion of VTE.

Select Inclusion Criteria:

- Patients 18 years or older who are seeking or receiving care of ALS at the Neuroscience Institute.
- Patients who are, by the clinical judgement of the investigator, are at high risk for developing a DVT (i.e. reduced mobility, extremity weakness, etc.)

Select Exclusion Criteria:

- symptomatic VTE at enrollment
- acute stroke within the previous 3 months prior to enrollment
- For subjects who are on anticoagulation therapy, the dose must be stable for at least 3 months before enrolling in the trial. Bulbar-onset disease.

NIH Site: clinicaltrials.gov/ct2/show/NCT04650087

Study ID: CRP21026

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Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of the Effect of Anti-CD14 Treatment in Hospitalized Patients with COVID-19 (DAIT-COVID -19-003)

Treatment Arm(s):

Experimental: anti-CD14 + SOC

Anti-CD14: 150 participants randomized to 4 mg/kg on Day 1, 2 mg/kg on Days 2-4 intravenously.

Standard of Care (SOC): All participants will receive remdesivir (antiviral) according to current approved dosing for COVID-19 illness.

Placebo Comparator: Placebo + SOC

150 participants randomized to Placebo diluent on Days 1-4 intravenously.

Standard of Care (SOC): All participants will receive remdesivir (antiviral) according to current approved dosing for COVID-19 illness.

Select Inclusion Criteria:

- Presence of SARS-CoV-2 infection documented by positive RT-PCR testing or history of positive RT-PCR test for SARS-CoV-2 within 7 days of screening
- Radiologic findings compatible with diagnosis of SARS-CoV-2 pulmonary infection

Select Exclusion Criteria:

- Receiving non-invasive positive-pressure ventilation through nasal mask, face mask, or nasal plugs
- Anticipated survival <48 hours

NIH Site: clinicaltrials.gov/ct2/show/NCT04391309

Study ID: CRP21014

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Prospective Evaluation of DVT Incidence and Risk Factors in Patients with ALS: A Pilot Study

Treatment Arm(s):

In this study, we aim to prospectively quantify the incidence and additional risk factors of VTE in our ALS population. Our secondary objective is to characterize the accuracy of D-dimer testing for exclusion of VTE.

Select Inclusion Criteria:

- Patients 18 years or older who are seeking or receiving care of ALS at the Neuroscience Institute.
- Patients who are, by the clinical judgement of the investigator, are at high risk for developing a DVT (i.e. reduced mobility, extremity weakness, etc.)

Select Exclusion Criteria:

- symptomatic VTE at enrollment
- acute stroke within the previous 3 months prior to enrollment
- For subjects who are on anticoagulation therapy, the dose must be stable for at least 3 months before enrolling in the trial. Bulbar-onset disease.
- concomitant cognitive disorders

Study ID: CRP17109

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**RAD-PD: Registry for the Advancement of Deep Brain Stimulation in Parkinson's Disease***Treatment Arm(s):*

- A. Individuals diagnosed with idiopathic PD
- B. Candidate for DBS treatment of PD as determined by the site investigator(s)

Select Inclusion Criteria:

- Individuals diagnosed with idiopathic PD
- Candidate for DBS treatment of PD as determined by the site investigator(s)

Select Exclusion Criteria:

- Individuals with prior history of DBS or lesion surgery
- Individuals who are unwilling or unable to participate in serial follow-up assessments as desired in the schedule of activities
- Individuals who are unable or unwilling to engage in completion of patient reported outcome measures, even with the assistance of a care provider

Study ID: CRP19039

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NEUROLOGY/NEUROSURGERY

Multiple Sclerosis

An Observational Study of Ocrelizumab-Treated Patients with Multiple Sclerosis to Determine the Incidence and Mortality Rates of Breast Cancer and all Malignancies (VERISMO Study)

Primary objective(s):

- To determine the incidence rate of breast cancer and all malignancies following the first ocrelizumab treatment among patients with MS
- To determine the mortality rate of breast cancer and all malignancies following the first ocrelizumab treatment among patients with MS
- To determine the event rate of all SAEs in the ocrelizumab-treated patients with MS

Select Inclusion Criteria:

- Aged 18 years or older
- Have a diagnosis of MS
- Newly treated with ocrelizumab (within 30 days before baseline visit [study entry]) according to the local label irrespective of the reason for starting ocrelizumab (ocrelizumab cohort)
- Newly treated with one of the following 6 approved MS DMTs: alemtuzumab, cladribine, dimethyl fumarate, fingolimod, natalizumab, or teriflunomide (within 30 days before baseline visit [study entry]) according to the local label irrespective of the reason for starting a new MS DMT (internal comparator cohort)

Study ID: CRP21009

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SIJ Stabilization in Long Fusion to the Pelvis: Randomized Controlled Trial

Treatment Arm(s):

- A. Multilevel Lumbar Fusion Surgery with additional placement of iFuse 3-D in a trajectory parallel to the S2AI screw

Select Inclusion Criteria:

- Age 21-75 at time of screening
- Patient scheduled for multilevel (>3 levels) spinal fusion surgery with planned fixation to the pelvis using S2AI screws
- Patient has signed study-specific informed consent form
- Patient has the necessary mental capacity to participate and is physically able to comply with study protocol requirements

Select Exclusion Criteria:

- Prior sacroiliac joint fusion/fixation on either side
- Any known sacral or iliac pathology
- Severe osteoporosis
- Known allergy to titanium or titanium alloys
- Patient currently receiving or seeking short- or long-term worker's compensation and/or currently involved in injury litigation related to the SI joint or low back pain.
- Currently pregnant or planning pregnancy in the next 2 years

NIH Site: clinicaltrials.gov/ct2/show/NCT04062630

Study ID: CRP19118

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NEUROLOGY/NEUROSURGERY

Neurosurgery

Pre-Operative Iron Supplementation in Patients Undergoing Multilevel Thoracolumbar Spinal Fusion Surgery - A Randomized Controlled Trial

Primary Objective(s):

- A. To determine whether pre-operative iron supplementation decreases the quantity of allogeneic pRBC units transfused during the intra-operative and post-operative period in patients undergoing multi-level thoracolumbar spinal fusion
- B. To measure peri-operative changes in iron level markers (serum ferritin, serum iron, transferrin, hemoglobin, hematocrit, total iron binding capacity) during the peri-operative period in patients undergoing multi-level thoracolumbar spinal fusion

Select Inclusion Criteria:

- Male or female ≥ 18 years of age at the time of surgery
- Greater than or equal to three levels of open thoracolumbar spinal fusion.

Select Exclusion Criteria:

- Patients already taking iron supplementation at the time of their initial consultation
- Patients undergoing urgent surgery within 4 weeks of their first encounter
- Patients taking Erythropoietin

Study ID: CRP20049

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Medtronic Product Surveillance Registry

Primary Objective(s):

- To characterize patient outcomes
- To identify device failures, adverse events or adverse event trends
- To characterize patterns of product use
- To characterize predictors of performance and effectiveness
- To identify potential signals for emerging performance issues

Select Inclusion Criteria:

- Patient or legally authorized representative (LAR) provides authorization and/or consent per institution and geographical requirements
- Patient has, or is intended to receive or be treated with, an eligible Medtronic product (Section 4.3)
- Patient is consented within the enrollment window of the therapy received, as applicable

Select Exclusion Criteria:

- Patient who is, or is expected to be, inaccessible for follow-up
- Patient is excluded by local law
- Patient is currently enrolled in, or plans to enroll in, any concurrent drug/device study that may confound the PSR results (i.e. no required intervention that could affect interpretation of all-around product safety and/or effectiveness)

NIH Site: clinicaltrials.gov/ct2/show/NCT01524276

Study ID: IRB12147

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MIND: Artemis in the Removal of Intracerebral Hemorrhage

Treatment Arm(s):

- A. Artemis + Medical Management (MIS)
- B. Best Medical Management Alone (MM)

Select Inclusion Criteria:

- Supratentorial ICH of volume ≥ 20 and ≤ 80 cc (measured using A x B X C/2 method)
- Hemostasis (hemorrhage increase of < 5 cc as confirmed by 2 CT/MR taken a minimum of 6 hours apart)
- NIHSS ≥ 6
- Presenting GCS ≥ 5 and ≤ 15
- Historical mRS 0 or 1
- Symptom onset < 24 hours prior to initial CT
- MIS must be initiated within 72 hours of ictus/bleed
- SBP must be < 180 mmHg and controlled at this level for at least 6 hours

NIH Site: clinicaltrials.gov/ct2/show/NCT03342664

Study ID: CRP17117

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Single-Sided Deafness and Asymmetric Hearing Loss Post-Approval Study

Treatment Arm(s):

- A. Study Procedure
Device: MED-EL Cochlear Implant System
Cochlear implant and audio processor

Select Inclusion Criteria:

- 5 Years and older
- Unilateral profound hearing loss, as defined by a pure-tone average (500, 1000, 2000, and 4000 Hz) of 90 dB or greater in the ear to be implanted
- Sensorineural hearing loss in the ear to be implanted, as defined by an air-bone gap less than or equal to 10 dB at two or more frequencies out of 500, 1000, 2000, and 4000 Hz and a diagnosed pathology of the outer or middle ear

Exclusion Criteria:

- Duration of profound hearing loss of 10 years or more
- Absence of cochlear development or non-functionality of cochlear nerve
- External or middle ear infection
- Other medical contraindication for surgery or anesthesia

NIH Site: clinicaltrials.gov/ct2/show/NCT04506853

Study ID: CRP20082

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RHEUMATOLOGY

Multiple Sclerosis

A Multicenter, Longitudinal, Open-Label, Single-Arm Study Describing Cognitive Processing Speed Changes in Relapsing Multiple Sclerosis Subjects Treated With Ozanimod (RPC-1063)

Treatment Arm(s):

- A. Patients with relapsing MS will receive RPC-1063 orally

Select Inclusion Criteria:

- Subject is male or female 18 to 65 years of age (inclusive) at the time of signing of the ICF.
- Subject has a diagnosis of MS according to the 2010 or 2017 Revised McDonald criteria.
- Subjects has ≤ 5 years since time of RMS diagnosis.
- Subject has ≤ 1 approved RMS DMT at time of study entry.

Select Exclusion Criteria:

- Subject has a visual or other sensorimotor impairment likely to confound test performance.
- Subject has a presence of > 10 GdE lesions on the Baseline brain MRI scan.
- Subject has a history of developmental disorder (eg, attention-deficit/hyperactivity disorder [ADHD], learning disability).

NIH Site: clinicaltrials.gov/ct2/show/NCT04140305

Study ID: CRP20009

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Neuspera's Implantable Sacral Neuromodulation (SNS) System in patients with symptoms of overactive bladder (OAB)

Select Inclusion Criteria:

- 22 years of age and older
- BMI between 18 and 35
- 6 months' history of urinary urgency incontinence diagnosis
- Failed conservative therapy and second-line drug therapy and is not a candidate for additional conservative or second-line therapy

Select Exclusion Criteria:

- Current urinary tract mechanical obstruction (e.g. benign prostatic hypertrophy, prostate cancer or urethral stricture)
- Has a predominance of stress urinary incontinence
- Any neurological condition that could interfere with normal bladder function, including stroke, epilepsy, multiple sclerosis, Parkinson's disease, or spinal cord injury
- Pelvic organ prolapse stage 3 or higher
- Previously implanted with a sacral neuromodulation device
- Any other active implanted devices (e.g. drug delivery pumps, pacemaker, ICD) whether turned on or off.
- Treatment of urinary symptoms with Botox within 12 months

NIH Site: clinicaltrials.gov/ct2/show/NCT04232696

Study ID: CRP19101

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UROLOGY

Stress Urinary Incontinence

CELEBRATE: An Adaptive, Two Stage, Double-Blind, Stratified, Randomized Controlled Comparing the Safety and Efficacy of AMDC-USR with Placebo in Female Subjects with Stress Urinary Incontinence

Select Inclusion Criteria:

- 50 to 75 years of age with primary and moderate-to-severe symptoms of stress urinary incontinence
- 6 months' history of stress urinary incontinence diagnosis
- Has a history of inefficient, insufficient, or refused pelvic floor muscle training (PFMT)

Select Exclusion Criteria:

- BMI \geq 35
- A medical diagnosis of fibromyalgia, uncontrolled diabetes (hemoglobin A1c $>7\%$), requires prophylactic antibiotics for chronic UTI's, cystitis or urethritis
- History of cancer in pelvic organs, ureters, or kidneys
- Systemic neuromuscular disorder (e.g. multiple sclerosis, Parkinson's disease)
- Actively undergoing treatment with stimulation neuromodulation system within the last 6 months
- Surgical intervention in the pelvic area within the last 6 months

NIH Site: clinicaltrials.gov/ct2/show/NCT03104517

Study ID: CRP17058

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