

| Cancer Centre | Study | Description | Cancer Type | Status of Trial |
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| Cross Cancer Institute | PET Pro (Choline PET) | Patients with localized prostate cancer are routinely treated with radiation therapy to the entire prostate gland. The investigators can identify where the cancer is concentrated in the prostate gland using a newer specialized imaging technique called 11C Choline PET (stands for choline positron emission tomography). This is different from the older type of PET scan that has been used in the past (called FDG PET) which has not been as accurate as the new PET scan for identifying where the cancer is in the prostate gland. It has also been shown that delivering higher doses of radiation to prostate cancer cells in the prostate have resulted in better cure rates in patients with prostate cancer. Therefore for goal number one the investigators want to give higher radiation dose to the prostate cancer cells. But the challenge has been that delivering higher doses of radiation to the prostate gland may also increase the chance of complications from the higher doses of radiation to the rectum, bladder and surrounding area. Therefore for goal number two the investigators want to minimize radiation dose to the rectum, bladder and surrounding area. 3-Tesla Magnetic Resonance Imaging (3T MRI) is a new kind of scan that will be used in this study to identify the urethra in the prostate so that the investigators can minimize the radiation dose to the urethra. The investigators believe the 3T MRI scan is able to point to the areas of cancer that may be able to predict how well the treatments may work, as well as which areas of the tumor appear to be responding to failing. | Genitourinary | Study Completed |
| Cross Cancer Institute | DIBH (Breath Hold) | Patients with left-sided breast cancer who receive adjuvant breast or chest wall radiation have increased risk of treatment related cardiovascular morbidity. The risk of cardiac morbidity and mortality is increased when a patient receives radiation following adjuvant chemotherapy and Herceptin. The dose-volume histogram (DVH) parameters associated with increased cardiac toxicity include volume of heart irradiated, total radiation dose received by the left ventricle (LV), V25 and mean cardiac dose. Even though modern RT treatments like 3DCRT and IMRT can reduce the mean dose to the heart, the maximum dose to the left side of the heart/LV may not be reduced if the target is close to the heart. The hypothesis is that DIBH RT can safely and effectively reduce the heart dose, especially the dose to the LV, that could lead to reduction in the incidence of radiation induced cardiovascular morbidity and mortality. | Radiation Therapy (Breast) | Study Completed |
| Cross Cancer Institute | LYNC | Lymphedema (significant arm swelling on the surgical side) is one of the most common complications following treatment for breast cancer. The impact of lymphedema is profound, resulting in negative self image, increased anxiety and poorer quality of life. In time, lymphedema can result in recurrent infections in the arm, functional impairment and pain. Approximately 21% of women who undergo breast cancer treatment develop lymphedema. Unfortunately this is a life-time condition which tends to worsen over time. Currently, treatment consists of intensive physiotherapy, meant to reduce the arm volume followed by the wearing of compression sleeves during the day for maintenance. This study hopes to show that the addition of night-time compression creates a measurable reduction in arm volume and that adding night-time compression to the standard care (daytime compression only) will produce improvements in quality of life for breast cancer survivors. | Breast | Study Completed |
| Cross Cancer Institute | PREMIUM | In current clinical practice, an acceptable standard treatment for locally advanced prostate cancer is radiation therapy in combination with hormone therapy (called Treatment B or Group B in this study). However, despite our best treatments, there is a risk that the prostate cancer may eventually return. As well, the hormonal therapy that is given to treat the prostate cancer is known to cause some harmful effects, with some patients using the hormones gaining weight, developing diabetes, having increased cholesterol levels, having increased blood pressure, and/or heart problems. This study is looking at whether Metformin, a drug that is commonly used to treat diabetes, can prevent patients from developing some of the harmful effects of the hormonal therapy. In treating diabetes, Metformin is known to decrease patients' sugar levels and also prevents patients from gaining weight, decreases their cholesterol levels, decreases the number of heart problems and allows patients to live longer. As a result, the researchers in this study are hopeful that Metformin will also be beneficial for men with prostate cancer on hormonal therapy by preventing them from developing these problems. | Genitourinary | Study Completed |
| Cross Cancer Institute | PRESTO | Breast cancer is a heterogeneous disease that includes two ER+ genetic subtypes (luminal A and luminal B) that differ in their response to treatment. Results from the Women's Health Initiative Trial showed that estrogen treated hysterectomized women with no prior history of breast cancer, had a significant and persistent decrease in breast cancer incidence when compared to placebo treated participants. This implies that some ER+ breast cancers are in fact growth inhibited by estrogens and are not growth promoted. The hypothesis of this study is that some ER+ breast cancers (luminal A) are actually sensitive (growth inhibited) by estrogen. Objectives: 1. To assess changes in breast cancer proliferation after a two-week trial of estradiol in newly diagnosed estrogen receptor positive post-menopausal breast cancer patients prior to surgery. 2. Exploratory analysis of biologic correlates with comparison to available genotyping tests. | Breast | Closed (Accrual Complete) |
| Cross Cancer Institute | GBM | Hypofractionated radiation therapy (RT) in the treatment of patients with glioblastoma, 18 - 70 years of age with good performance status (ECOG 0 - 2), will be well tolerated and yield survival non-inferior to conventional fractionated RT, allowing significant abbreviation of the length of the radiation course required for these patients with limited survival. The importance of hypofractionation is, therefore, not in improving survival, but rather to shorten RT duration to improve patient comfort and convenience. This approach is pertinent given the limited life expectancy of glioblastoma and has been used in patients with prolonged survival including breast and prostate cancers. | Central Nervous System | Closed (Patients in Follow-Up) |
| Cross Cancer Institute | 3D MRI | The purpose of this pilot study is to test new magnetic resonance imaging (MRI) acquisition and processing techniques on primary brain tumor patients. The objectives are to improve image-guided radiation therapy (IGRT) planning (first part of the study) and treatment monitoring (second part). | Central Nervous System | Study Completed |
| Cross Cancer Institute | CIPNN (Omega 3) | The trial will utilize Nutraceuticals (Vitamin D 2000IU oral once daily, Vitamin B6 100 mg oral once daily, Vitamin B12 100 mcg oral once daily, Omega-3 Fatty Acids 900 mg oral three times a day) in patients treated with Docetaxel as Neoadjuvant or Adjuvant Breast cancer Therapy. The trial is being conducted to see if the use of Nutraceuticals will prevent or reduce Chemotherapy Induced Peripheral Neuropathy (CIPN). | Breast | Study Completed |
| Cross Cancer Institute | MENAC | Cancer cachexia is a multi-factorial syndrome defined by an ongoing loss of skeletal muscle mass (with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment. There is an urgency for improving management, but there is no consensus on the optimal treatment for cancer cachexia. Several single therapies for cancer cachexia have been examined in clinical trials, with disappointing overall results. As multiple factors are responsible for the development of cachexia, it has been argued that optimal cachexia interventions should target all components: multimodal therapy for a multimodal problem. The overall aim of this study is to early prevent the development of cachexia rather than treatment late in the disease trajectory. From a patient perspective a short term effect will be to improve physical and psychological function, to reduce symptom burden and to improve survival. In other words live a longer and better life during and after chemotherapy. Direct effects of the cachexia intervention are expected to be reduction of weight and muscle loss, and improved physical activity and quality of life. | Basket Study (NSCLC, pancreatic adenocarcinoma) | Open to Accrual |
| Cross Cancer Institute | OZM-064 STARC | The standard treatment of locally advanced rectal cancer involves neoadjuvant chemoradiation therapy (CRT) followed by surgery and further adjuvant chemotherapy. The pathologic complete responses associated with neoadjuvant CRT are 10-20%. The prognosis of patients undergoing neoadjuvant CRT is associated to the extent of post-treatment tumour regression, the final primary tumour stage and presence of involved lymph nodes in the surgical specimen. This data suggests that treatments that enhance the pathological response may result in improvements in survival. Overwhelming preclinical and clinical evidence suggests that statins demonstrate anticancer properties and sensitize cancer tissues and protects normal tissues to the effects of radiation. Hence, we hypothesize that the addition of rosuvastatin to standard CRT for the treatment of locally advanced rectal cancer may improve the pathological response rate. This protocol describes an open-label single-arm phase 2 study designed to test this hypothesis. Moreover, this study will also identify genetic, serological, and pathological biomarkers that may be both prognostic and predictive of response and toxicity to treatment. This study is designed to include minorities as appropriate, but as it is not randomized it is not designed to measure differences in intervention effects. Due to significant increased risk for myopathy/rhabdomyolysis in the Asian population, these patients will not be included in this study for safety reasons(56). Asian patients (having either Filipino, Chinese, Japanese, Korean, Vietnamese or South Asian origin) may be at greater risk of developing muscle-related adverse events, including rhabdomyolysis, with rosuvastatin. In a recent U.S. study, levels of rosuvastatin were found to be approximately two times greater in Asian Americans when compared to a Caucasian control group. | Gastrointestinal | Open to Accrual |
| Cross Cancer Institute | RATIO | Melanoma lesions often contain a high number of infiltrative T-cells specific to melanocyte tumor associated antigens such as MART1, gp-100, and tyrosinase. There is a clinical impact of the location and type of immune cells within colorectal cancer and this may also occur in melanoma. Not all lymphocytes are created equal, and to discern one subset from another is technically challenging and requires a high degree of labor and skill. Recent advances to fight melanoma have led to improvements in survival and the potential for long term remissions. These new treatments are known as immune checkpoint inhibitors. These treatments are expensive and not all patients will benefit from them. This study is being conducted to see whether analysis of the genes associated with inflammation and transplant rejection will help predict which patients may benefit when treated with immune checkpoint inhibitors (i.e. those patients whose tumors will respond to treatment versus those who do not). | Melanoma | Closed (Patients in Follow-Up) |

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| Cross Cancer Institute | LATENT | <p>Up to 20% of all cancers may be associated with a bacterial or viral infection. In some instances, the infection may be one of the reasons why the cancer developed in the first place. One such example is infection with the human papilloma virus (HPV) and the development of cervical or oral cavity cancer.</p> <p>A viral infection that is chronic may not cause a person symptoms, and may be able to escape detection by a person's own immune system. One of the medications being studied in this clinical trial (Valproic acid) may be able to unmask a chronic viral infection from a person's own immune system, therefore making the virus susceptible to attack by the immune system. In this study Valproic acid is being combined with an immune therapy, Avelumab. Avelumab is an antibody that targets a person's own immune cells, or lymphocytes. Lymphocytes must be activated to fight infections or cancer, but after activation they are deactivated. Avelumab prevents the deactivation of a lymphocyte, in effect "turning off the off-switch." This leads to a re-energizing of a person's immune system, hopefully leading to an attack by the immune system on a person's cancer.</p> <p>Avelumab is known to be an effective treatment for a variety of cancers, although it has not yet been tested in all cancers. By combining Valproic acid, a treatment which targets the virus that contributed to the development of this type of cancer with Avelumab the investigators hope to enhance the ability of Avelumab to restore the body's own immune defense against the cancer.</p> | Basket Study (16-positive SCCHN, cervical cancer, p16-positive vulvar or vaginal SCC, p16-positive anal canal cancer, p16-positive penile cancer, or EBV-positive NPC, EBER-positive Hodgkins and non-hodgkins lymphoma) | Closed (Patients in Follow-Up) |
| Cross Cancer Institute | Imatinib 1.0 | <p>Thyroid cancers that have spread beyond the neck are not curable. About 30,000 people worldwide die from thyroid cancer every year. Usually, thyroid cancers get worse because the cancer cells become more and more abnormal through a process that is called dedifferentiation. Radioactive iodine is a standard treatment for this type of thyroid cancer. Patients will usually receive multiple dose of radioactive iodine over the course of their cancer journey. Radioactive iodine does not work as well in cancers that progress/worsen. When this occurs, the radioactive iodine treatments no longer work against the cancer and the cancer grows. Imatinib is an anti-cancer drug that blocks receptor function. It has been used for many years to treat other cancers such as leukemia. The investigators who wrote this study believe that, based on laboratory testing, if thyroid cancer patients are given imatinib after their cancers have become resistant to radioactive iodine, the imatinib will block the appropriate receptor allowing the radioactive iodine into the cancer cells. This should shrink the tumours. Shrinking the tumours and would mean longer control of the cancer, helping people with this disease live longer</p> | Thyroid | Open to Accrual |
| Cross Cancer Institute | IIT-0002 Fine Art | <p>A novel nutritional supplement has been shown in previous studies to protect patients from treatment side effects while also improving the benefit of chemotherapy. This same supplement has been shown to slow or stop muscle loss in cancer patients, improving their daily function and quality of life. These results have been found in small studies; therefore larger, well-designed studies are required so that the results can be confirmed and translated to a clinical practice setting. Our research study at the Cross Cancer Institute aims to confirm whether this novel nutrient, along with chemotherapy or immunotherapy, can improve the benefit of treatment while preserving muscle and function for patients.</p> | Radiation Therapy (Head and Neck cancer) | Open to Accrual |
| Cross Cancer Institute | IIT-0005 DHA-WIN | <p>Docosahexaenoic acid (DHA) is an omega-3 long chain polyunsaturated fatty acid (n-3 LCPUFA). N-3 LCPUFA are essential fatty acids in the diet. The majority of n-3 LCPUFA in the diet is alpha-linolenic acid (ALA). While DHA can be synthesized from ALA and other n-3 LCPUFA in the body, endogenous synthesis is low. Consequently, the only way to significantly increase levels of DHA in tissues is by directly consuming this fatty acid. Common sources of DHA are fatty fish, fish oil and omega-3 supplements and fortified foods. DHA is readily incorporated into membrane phospholipids and induces changes in the properties of the cell membrane including altered fluidity; permeability and membrane transport as well as activity of membrane bound receptors and enzymes. It is well established that changes in membrane DHA has multiple effects in the body, including modulation of neurological, immune, and cardiovascular functions. In breast cancer, DHA increases sensitivity of breast cancer cells to different chemotherapeutic agents, and in animal models of breast cancer, dietary DHA decreases tumour growth. Our preclinical studies demonstrate that DHA increases efficacy of both doxorubicin and docetaxel, two agents commonly used in the adjuvant setting for breast cancer treatment. Furthermore, DHA mitigates chemotherapy induced weight loss in mice, and reduces paclitaxel toxicities in breast cancer patients, strongly indicating that DHA protects against toxicity in normal tissues. Directly relevant to this study, increased DHA in breast adipose tissue correlates with improved response to chemotherapy, and increased dietary intake of n-3 LCPUFA, including DHA, results in increased DHA incorporation in breast adipose tissue. Lastly, in advanced metastatic breast cancer, DHA supplementation correlated with improved outcomes in a subset of patients. Consequently, we hypothesize that the therapeutic index (efficacy: toxicity ratio) will be improved with the addition of DHA. In this clinical trial, we will investigate the benefit of DHA supplementation in combination with neoadjuvant chemotherapy in patients with early breast cancer.</p> <p>RESEARCH QUESTION & OBJECTIVES: We propose to evaluate incorporation of DHA in women with breast cancer in treatment naive patients in combination with chemotherapy, and assess potential benefit of DHA supplementation in breast cancer patients, using change in Ki67 labeling index (marker of proliferation) as a surrogate marker of efficacy. This study will further investigate the relationship between DHA in plasma phospholipids (as a potential biomarker of tumour incorporation) and effect on systemic immune function. Specific objectives are:</p> <ol style="list-style-type: none"> 1. Identify changes in prognostic biomarker Ki67 in breast cancer patients receiving high dose of DHA, compared to no supplementation, in combination with chemotherapy. 2. To assess DHA incorporation into plasma phospholipids in patients undergoing neoadjuvant chemotherapy treatment. 3. Examine changes in plasma cytokines, chemokines, inflammatory markers and systemic immune function following DHA supplementation in patients undergoing neoadjuvant chemotherapy 4. Examine factors that may influence DHA incorporation in breast cancer patients. 5. Examine changes in markers for apoptosis and stem cells (by immunohistochemistry) following DHA supplementation in patients undergoing neoadjuvant chemotherapy. 6. Describe rate of pathological complete response in resected breast tissue and axillary nodes in breast cancer patients receiving DHA | Breast | Open to Accrual |
| Cross Cancer Institute | IIT-0004 UNSCARRed | <p>The purpose of this study is to find out what effects the combination of radiation therapy and Avelumab have on this cancer. The effectiveness of this treatment as well as what side effects occur will both be studied. Squamous cell carcinoma of the skin is the most commonly diagnosed cancer. In the majority of instances, a minor surgical procedure is curative. Less commonly, squamous cell carcinoma cannot be removed surgically, due to the location and/or extent of the cancer, or due to patient-specific factors which would make surgery unsafe. When squamous cell carcinoma cannot be removed surgically, radiation therapy may serve as an effective alternative treatment. Squamous cell carcinomas are typically very sensitive to radiation, and in some instances radiation therapy may also cure a person of their cancer. While some people may be cured by radiation therapy, not all people are. This study is investigating the combination of radiation therapy and immune therapy. When given together, more patients may be cured of their cancer. Immune therapy is effective for the treatment of squamous cell carcinoma. In clinical trials, more than half of patients benefit from immune therapy. Immune therapy is not chemotherapy. Instead, immune therapy involves the infusion of antibodies which target a person's own immune system. Immune therapy "reactivates" a person's own immune system against their cancer. The treatment offered within this clinical trial includes daily radiation treatments as well as immunotherapy treatments administered once every two weeks. The immunotherapy in use is a drug called Avelumab, which is an antibody that helps the body's immune system fight cancer. Health Canada has not approved the sale or use of this product to treat this kind of cancer, although they have allowed its use in this study.</p> | Cutaneous | Open to Accrual |
| Cross Cancer Institute | IIT-0008 RT + Vertebroplasty | <p>Since patients with spinal metastases are living longer, durable palliation with long-term tumor control are becoming increasingly important.</p> <p>EBRT results in durable local control of bone metastasis. However, about 25 % of patients with spinal metastases only achieved complete pain relief following EBRT for a median duration of less than 4 months. This could be partly due to spinal instability. In addition, almost half of the patients who receive EBRT will subsequently develop VCFs. Hence, RT does not stabilize the spine secondary to VCFs and is not effective in preventing imminent VCFs. Vertebroplasty has rapidly reduced pain and improved function in patients with VCFs. However, vertebroplasty does not provide local tumor control similar to EBRT.</p> <p>It is theorized that combining vertebroplasty with EBRT will stabilize the spine, relieve the pain, prevent imminent VCFs and minimize or avoid the need for opioids. It is hypothesized that combining a spine stabilization procedure such as vertebroplasty with RT will be the most effective management for patients with spinal metastases than RT alone for patients with spinal metastases. Combined vertebroplasty and radiotherapy is not a standard treatment option at present. This study is designed to quantify the advantage of adding vertebroplasty to radiotherapy for patients with spinal metastases. If the study is proven to be significant, it could become the standard of care for patients with spinal metastases.</p> | Radiation Therapy (basket study) | Open to Accrual |

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| Cross Cancer Institute | IIT-0009 NivoPlus | <p>Rationale for conducting the study: The treatment of patients with SCCHN is challenging, and represents an area of high unmet need. Treatment options within this patient population are limited, and inadequately treated disease may cause high morbidity, negatively impacting quality of life and leading to increased costs for supportive care. To address the unmet needs of these patients, this exploratory trial combining pemtrexed with standard-of-care nivolumab, with an investigational plan to study clinical and health services outcomes is being proposed.</p> <p>Primary objectives: 1. Feasibility based on number of participants who complete at least 2 cycles of nivolumab in combination with pemtrexed. 2. Safety analysis (treatment-related and non-related adverse events per CTCAE v4.03, assessed by incidence and severity of adverse events, changes in laboratory findings, physical examinations, vital signs, and the number of discontinuations due to adverse events).</p> <p>Secondary objectives 1. Objective response rate associated with combination nivolumab/pemtrexed therapy (defined as the proportion of participants achieving either a partial response or a complete response as best-overall response per RECIST criteria 1.1). 2. Progression-free survival (defined as the time between the date of treatment initiation and the date of disease progression or death, whichever occurs first). 3. Overall survival (defined as the time between the date of treatment initiation and the date of death). 4. Patient-reported quality of life</p> <p>This study has been designed as a non-randomized, single-arm study to investigate the feasibility, safety and efficacy of standard of care nivolumab in combination with pemtrexed therapy in patients with unresectable SCCHN. An initial pilot of 6 participants will be undertaken for dose limiting toxicities. If 2 or more participants have defined dose limiting toxicities at the starting dose of 500mg/m2 of pemtrexed, then an adjustment of nivolumab-pemtrexed dosing/administration will occur. For any future participants enrolled on to the study, the starting dose of pemtrexed will be 400mg/m2. If less than 2 participants have a dose limiting toxicity, the 500mg/m2 dose of pemtrexed will be considered the recommended phase II dose and further participant enrollment will occur. There will be an interim analysis for response after 10 participants have been assessed for response; if the objective response rate is less than 20%, the study will be stopped and deemed futile.</p> | Head and Neck | Open to Accrual |
| Tom Baker Cancer Centre | PaRCus | <p>The primary study objective is to measure relief of dysphagia, defined as improvement of at least one point on the Mellow dysphagia scale. This will be measured at 9 weeks after the start of RT and must be maintained at the next review 4 weeks thereafter (week 13). Secondary study objectives include dysphagia progression-free survival, time to achieving any response in dysphagia after treatment, number of patients receiving secondary treatment, utility assessments and quality of life differences. Other objectives include examining acute and late toxicity and collecting serum for studies of tumor response and toxicity.</p> <p>All eligible and enrolled patients with non-curable cancer of the esophagus will receive external beam radiotherapy of 30Gy/10 fractions over two weeks and receive carboplatin (AUC 2) and paclitaxel (50 mg/m2) intravenously on days 1, 8.</p> | Gastrointestinal | Open to Accrual |
| Tom Baker Cancer Centre | OZM-064 | <p>The standard treatment of locally advanced rectal cancer involves neoadjuvant chemoradiation therapy (CRT) followed by surgery and further adjuvant chemotherapy. The pathologic complete responses associated with neoadjuvant CRT are 10-20%. The prognosis of patients undergoing neoadjuvant CRT is associated to the extent of post-treatment tumour regression, the final primary tumour stage and presence of involved lymph nodes in the surgical specimen. This data suggests that treatments that enhance the pathological response may result in improvements in survival. Overwhelming preclinical and clinical evidence suggests that statins demonstrate anticancer properties and sensitize cancer tissues and protect normal tissues to the effects of radiation. Hence, we hypothesize that the addition of rosuvastatin to standard CRT for the treatment of locally advanced rectal cancer may improve the pathological response rate. This protocol describes an open-label single-arm phase 2 study designed to test this hypothesis. Moreover, this study will also identify genetic, serological, and pathological biomarkers that may be both prognostic and predictive of response and toxicity to treatment.</p> <p>This study is designed to include minorities as appropriate, but as it is not randomized it is not designed to measure differences in intervention effects. Due to significant increased risk for myopathy/rhabdomyolysis in the Asian population, these patients will not be included in this study for safety reasons(56). Asian patients (having either Filipino, Chinese, Japanese, Korean, Vietnamese or South Asian origin) may be at greater risk of developing muscle-related adverse events, including rhabdomyolysis, with rosuvastatin. In a recent U.S. study, levels of rosuvastatin were found to be approximately two times greater in Asian Americans when compared to a Caucasian control group.</p> | Gastrointestinal | Open to Accrual |
| Tom Baker Cancer Centre | Pre-emptive Therapy of GVHD | <p>Graft-vs-host disease (GVHD) causes substantial mortality, morbidity and poor quality of life after blood or marrow transplantation (BMT). In Alberta, we use antithymocyte globulin (ATG, given on days -2, -1 and 0) in addition to methotrexate and cyclosporine for GVHD prophylaxis. In spite of that, ~40% patients develop significant GVHD (grade 2-4 acute GVHD or chronic GVHD needing systemic immunosuppressive therapy). ATG at the dose we typically use (4.5 mg/kg) is relatively non-toxic. At higher doses, ATG could increase the likelihood of posttransplant infections or relapse. Thus an extra dose of ATG (on top of the routine 4.5 mg/kg) might be justified only for patients at high risk of developing significant GVHD. In our experience, low serum level of interleukin-15 (IL15) and high serum level of interleukin-2 receptor alpha (IL2Ra) on day 7 predict development of significant GVHD. Here we will test whether, compared to historical/concurrent controls, an extra dose of ATG (3 mg/kg on day 8) given to patients with low IL15 or high IL2Ra on day 7 reduces the incidence of significant GVHD, and improves survival free of relapse and GVHD, and quality of life.</p> | Blood and Marrow Transplant | Closed (Accrual Complete) |
| Tom Baker Cancer Centre | SABR also known as SBRT | <p>Stereotactic Ablative Body Radiotherapy (SBRT) is an emerging technology that uses image guidance, breathing control and complex radiation therapy planning and delivery techniques to deposit high doses of radiation therapy to accurately-defined targets. The goal of this therapy is to sterilize all disease within the RT volume with minimal toxicity. Specific technical constraints of Surgery or RFA are not limitations for SBRT due to the physical properties of high energy photons. SBRT for oligo-metastasis has been reported to obtain 95% rates of 2-year local control, and 5 year survival up to 40% with acceptable toxicity. However, interpretation of the available studies in the context of mCRC is limited due to inclusion of multiple different pathologies and prior and concurrent systemic therapies.</p> <p>The proposed study will evaluate if "curative intent" SBRT can provide high response rates and clinically meaningful PFS with acceptable toxicity specifically in patient with mCRC who do not have surgical options and are no longer responding to systemic therapy.</p> <p>A major issue with all local ablative therapies is that disease can progress outside the treated area. To effectively select patients for SBRT, it would be desirable to have the capability to identify individuals with intra-hepatic disease that is radiosensitive in the absence of biologically aggressive extra-hepatic disease. It is possible that a particular pattern of circulating metabolites may inform the use of hepatic radiotherapy in mCRC by identifying patients at high risk of early systemic progression.</p> | Colorectal | Closed Early |
| Tom Baker Cancer Centre | HDMgem | <p>STUDY OBJECTIVE: To evaluate the safety and efficacy of infusional gemcitabine prior to high-dose melphalan as HDCT followed by autologous stem cell transplantation in patients with relapsed/refractory lymphoma.</p> <p>STUDY ENDPOINTS Primary: 1. 3-year PFS of relapsed/refractory lymphoma patients treated with infusional gemcitabine, high dose melphalan (Gem-Mel) and ASCT 2. Grade 3-4 non-hematological toxicity</p> <p>Secondary: 1. Overall survival 2. Cost-effectiveness as measured by in-hospital costs of Gem-Mel relative to historical controls treated in Calgary with BEAM or Melphalan+/-TBI. 3. Melphalan pharmacokinetics and outcome of Gem-Mel/ASCT a. Evaluate relationship between clinical factors and drug exposure b. Evaluate relationship between drug exposure and non-hematological toxicity and PFS c. Determine if a study evaluating pre-transplant pharmacokinetic test dosing would be warranted.</p> | Blood and Marrow Transplant | Open to Accrual |

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| Tom Baker Cancer Centre | ACCEL/ APBI 27/5 | <p>Various accelerated partial breast irradiation (APBI) techniques are available for women with early-stage breast cancer following breast conserving surgery (BCS). The goals of APBI are to improve convenience and decrease treatment burden for patients, reduce the volume of body receiving RT and decrease costs for the health system. The most accessible APBI technique is linear accelerator-based, 3D conformal RT. Large RCTs including the Canadian RAPID trial have completed accrual and over the next few years, will report on the tumor control efficacy of APBI compared to whole breast irradiation (WBI). With a median follow up of exceeding 5 years among 2185 patients on the RAPID trial the overall event rate excluding deaths from non cancer causes was 1.9% (J.Julien, RAPID statistician, July2015) This event rate includes local, regional and distant recurrences and contralateral breast cancer events. At least 1.5% of patients would be expected to have experienced a contralateral breast cancer event by 5 years so it is very likely that RAPID will eventually confirm, that among the low risk women treated in that protocol, even APBI can achieve a very low breast recurrence rate after breast conserving surgery (BCS). However, the dose and fractionation used (38.5Gy in 10 fractions, twice daily in 1 week) resulted in worse breast fibrosis and cosmesis. Over the decade since RAPID was designed, analyses of the long-term outcomes of various breast radiation therapy (RT) fractionation regimens have suggested that normal tissue fibrosis and cosmesis varies with the radiobiological constant: $\alpha/\beta=2$ rather than 3.4 which was assumed in the design of the RAPID trial. The linear-quadratic equation using $\alpha/\beta=2$, indicates that a dose of 27Gy in 5 daily treatments should result in comparable late effects as 42.5Gy in 16, or 50Gy in 25 fractions which are considered 'standard' whole breast RT prescriptions after BCS. A clinical trial initiated now to identify a convenient and less toxic 3D-conformal APBI technique will mean that Albertans with early-stage breast cancer will have access to appropriate APBI when the NSABP and RAPID randomized trials of 3D conformal APBI report equivalent efficacy to WBI.</p> | Breast | Closed (Accrual Complete) |
| Tom Baker Cancer Centre | LY.17 | <p>This is a multicentre, open-label randomized phase II trial of novel combination therapy in patients with relapsed and refractory aggressive B cell lymphoma, conducted by the CCTG with support of Janssen. The trial will compare conventional Rituximab, Gemcitabine, Dexamethasone, and Cisplatin (R-GDP) versus investigational salvage therapies. Additional investigational arms will be added over the course of the study.</p> | Hematology | Open to Accrual |
| Tom Baker Cancer Centre | OncoRe | <p>This study will assess whether the implementation of a combination of ERAS (Enhanced Recovery After Surgery) protocols and postoperative followup via a smartphone app can offer 1) improved patient satisfaction, 2) virtual patient monitoring without an increase in postoperative emergency room visits, number and severity of postoperative complications, and readmissions, 3) decreased healthcare system costs, and 4) improved patient convenience and reduced patient financial costs. The study will be conducted among women having mastectomy, breast reconstruction, and gynecological oncology procedures. Half of the participants will be assigned to physician monitoring via a smartphone app and half will receive conventional care.</p> <p>Other: Mobile app for follow-up care The mobile app follow-up care is an application that can be loaded onto a smartphone. It allows the patient to submit photos of their surgical site, QoR15 scores, and EORTC selected adverse events scores. The information collected is transmitted to members of the surgical team (i.e. the primary surgeon) and used to monitor recovery over the first 6 weeks following surgery.</p> <p>Other Name: QoC Health Inc. mobile application</p> | Breast | Open to Accrual |
| Tom Baker Cancer Centre | PROTECT | <p>This study is a phase II, single arm, prospective, multi-centre, cohort study designed to assess xerostomia-related quality of life at 12 and 24 months using reduced radiotherapy dose and treatment volumes in patients with p16+ oropharyngeal squamous cell carcinoma receiving chemoradiotherapy. This study will enrol 32 patients. Currently, the standard treatment for locally advanced head and neck squamous cell carcinoma is concurrent chemotherapy and radiotherapy to a dose of 70 Gy to the primary and gross nodal disease with a lower dose to subclinical disease. This study proposes to reduce the elective radiotherapy treatment volumes (i.e. omission of lb nodes) in conjunction with reduction of radiotherapy dose (from 70 Gy to 60 Gy) in the definitive treatment of primary squamous cell carcinoma of the oropharynx in p16+ patients.</p> <p>Secondary objectives are:</p> <ul style="list-style-type: none"> • To determine rates and patterns of failure and survival at 12 and 24 months. • To determine acute and late toxicities. • To determine acute and late quality of life as measured by MDASI-HN and MDADI. • To assess changes in swallowing function as identified by fibre-optic endoscopic evaluation of swallowing or modified barium swallow at 24 months using penetration aspiration scale (PAS). | Head and Neck | Open to Accrual |
| Tom Baker Cancer Centre | GZ-2016-11623 | <p>The purpose of this study is to find out whether compared to our standard low dose ATG with CSA, the high dose ATG without CSA minimizes the chances of relapse and chronic GVHD, without increasing the chances of other transplant complications.</p> <p>There are a number of complications of allogeneic hematopoietic cell transplantation. The main complications are: Recurrence (relapse) of the disease for which the transplantation is done (for example, leukemia). The relapse usually leads to death. Acute graft-versus-host disease (GVHD). This may lead to death. Chronic GVHD. This may lead to poor quality of life long-term.</p> <p>This study is being done to minimize the chances of patients getting relapse and chronic GVHD, without increasing the chances of getting acute GVHD.</p> <p>At this time, the standard of care approach to treat this condition would be with: Low dose thymoglobulin (ATG), given on Day -2, -1 and 0. Cyclosporin (CSA), given from Day -1 through to Day 84. Methotrexate, given on Days 1, 3, 6 and 11 CSA reduces the chances of getting acute GVHD, but it does not reduce the chances of getting chronic GVHD and increases the chances of getting relapse. ATG reduces both acute and chronic GVHD, and does not increase relapse. In this study, high dose ATG will be given on days -4, -3, -2, -1 and 0 (instead of only on days -2, -1 and 0), no CSA (instead of CSA from day -1 through 84) will be given, and the routine dose of methotrexate (unchanged) will be given. We think that this may lead to better outcomes. Patients will be followed per standard practice of the Alberta Blood and Marrow Transplant Program for the development of acute and chronic GVHD, and for relapse. Patients will also be asked to complete a quality of life questionnaire 2 years after the transplant to assess how their treatment and illness affects their quality of life.</p> | Blood and Marrow Transplant | Accrual Paused |