Androgen Suppression Combined With Nodal Irradiation and Dose Escalated Prostate Treatment

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Histologically confirmed adenocarcinoma of the prostate diagnosed within the last 9 months * Participants with unfavourable risk prostate cancer are eligible according to the following NCCN classification guidelines (Version 4.2022

•May 10, 2022): • Unfavourable-intermediate risk

•has one or more of the following: * 2 or 3 Intermediate Risk Factors (IRFs): cT2b-cT2c, Gleason 7 (grade group 2 or 3), and/or PSA 10-20 ng/ml; * Gleason 4+3 (grade group 3) * \> 50% biopsy cores positive • High risk

•has one of the following: * cT3a * Gleason 8-10 (grade group 4 or 5) * PSA \> 20 ng/ml • Very-high risk

•has at least one of the following: * cT3b-cT4 * Primary Gleason pattern 5 * 2 or 3 high risk features: cT3a, Gleason 8-10 (grade group 4 or 5), and/or PSA \> 20 ng/ml * \> 4 cores with Gleason 8-10 (grade group 4 or 5) * ECOG performance status of 0, 1 or 2 * Participants must be ≥ 18 years of age * Judged to be medically fit for brachytherapy * Participant is able (i.e. sufficiently fluent) and willing to complete the quality of life and/or health utility questionnaires in either English, French or Spanish * Participants consent must be appropriately obtained in accordance with applicable local and regulatory requirements. Each participant must sign a consent form prior to enrollment in the trial to document their willingness to participate * Participants must be accessible for treatment and follow-up. Investigators must assure themselves the participants enrolled on this trial will be available for complete documentation of the treatment, adverse events, and follow-up * In accordance with CCTG policy, protocol treatment is to begin within 12 weeks of participant enrollment * Participants must be willing to take precautions to prevent pregnancy while on study * ADT (LHRH agonists, antagonists, or anti-androgens) for prostate cancer is permitted for up to 30 days before study enrollment * 5-alpha reductase inhibitors (5-ARI) are allowed, but baseline PSA will be corrected if 5-ARI use occurs within 6 months of enrollment * Participants may NOT have received other therapies including chemotherapy, PARPi, radioligand or other investigational drugs for prostate cancer * Participants with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial * Urinary function defined as International Prostate Symptom Score (IPSS) \< 20. Alpha blockers are allowed to treat baseline urinary function * HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial

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Exclusion Criteria:

* Prior pelvic radiotherapy * Contraindication to radical prostate radiotherapy (e.g. connective tissue disease or inflammatory bowel disease) * Anticoagulation medication (if unsafe to discontinue for gold seed insertion or brachytherapy implant) and/or prior or current bleeding diathesis * Prior steam vaporization (Rezum), transurethral resection of the prostate (TURP), prostatectomy (simple or radical), or any ablative therapy to the prostate (cryotherapy, HIFU, TULSA, focal laser ablation, photodynamic therapy) * Prostate volume \> 60cc before start of androgen deprivation therapy * Anatomy that would preclude precise brachytherapy implant (such as arch interference or large median lobe) * Evidence of castrate resistance (defined as a rising PSA \> 3.0 ng/ml while testosterone is \< 3.0 nmol/l) * Hip prosthesis (unilateral hip replacement is allowed if dose constrains can be reasonably achieved.

Conditions & Interventions

Interventions:
RADIATION: Radiation, RADIATION: Radiation SBRT only, DRUG: ADT
Conditions:
Prostate Cancer

More Information

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