**Protocol Title:** Phase III Randomized Trial of Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer

**Target Population:** Prostate Cancer

**Summary:** Demonstrate that Prophylactic, Neoadjuvant, Androgen-Deprivation Therapy (NADT) and Whole-Pelvic Radiation Therapy (WPRT) will result in improvement in Overall Survival (OS) of patients with "Unfavorable" Intermediate-Risk or "Favorable" High-Risk Prostate Cancer compared to NADT and High-Dose Prostate (P) and Seminal Vesicle (SV) Radiation Therapy (RT) using Intensity-Modulated RT (IMRT) or External-Beam RT (EBRT) with a High-Dose Rate (HDR) or a Permanent Prostate (radioactive seed) Implant (PPI) boost.

**Key Inclusion Criteria:**
- Pathologically (histologically or cytologically) proven diagnosis of Prostatic Adenocarcinoma within 180 Days of registration at Moderate-Risk to High-Risk for recurrence as determined by 1 of the following combinations:
  - Gleason score 7-10 + T1c-T2b (palpation) + prostate-specific antigen (PSA) < 50 ng/mL
  - Includes Intermediate-Risk and High-Risk patients
  - Gleason score 6 + T2c-T4 (palpation) + PSA < 50 ng/mL OR
  - Gleason score 6 + ≥ 50% (positive) biopsies + PSA < 50 ng/ml
  - Gleason score 6 + T1c-T2b (palpation) + PSA > 20 ng/mL
- Note: Patients previously diagnosed with Low-Risk Prostate Cancer undergoing active surveillance who are re-biopsied and found to have unfavorable Intermediate-Risk Disease or favorable High-Risk Disease according to the protocol criteria are eligible for enrollment within 180 Days of the repeat biopsy procedure.
- Clinically negative lymph nodes as established by imaging (Pelvic and / or Abdominal CT or MRI), but NOT by Nodal Sampling or Dissection, within 90 Days prior to registration.
  - Patients with lymph nodes equivocal or questionable by imaging are eligible if the nodes are ≤ 1.5 cm.
  - Patients status post a negative lymph node dissection are not eligible.
- No evidence of Bone Metastases (M0) on Bone Scan within 120 Days prior to registration.
  - Note: NaF PET / CT is an acceptable substitute.
  - Equivocal Bone Scan findings are allowed if Plain Films (or CT or MRI) are negative for metastasis.

**Key Exclusion Criteria:**
- Prior history of Bladder Cancer.
- Prior Hematological Malignancy.
- Previous Radical Surgery (Prostatectomy) or Cryosurgery for Prostate Cancer.
- Previous Pelvic Irradiation, Prostate Brachytherapy, or Bilateral Orchiectomy.
- Previous Hormonal Therapy, such as LHRH Agonists or LHRH Antagonist or Anti-Androgens, Estrogens, or Surgical Castration.
- Prior Pharmacologic Androgen Ablation for Prostate Cancer.
  - Exception: Allowed if the onset of Androgen Ablation ≤ 45 Days prior to the date of registration.
- Finasteride within 30 Days prior to registration.
- Dutasteride or Dutasteride / Tamsulosin (Jalyn) within 90 Days prior to registration.
- Prior or Concurrent Cytotoxic Chemotherapy for Prostate Cancer
  - Note: Prior Chemotherapy for a different cancer is allowable.
- Prior Radiotherapy, including Brachytherapy, to the region of the study cancer that would result in overlap of radiation therapy fields.

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**For additional information:** [https://clinicaltrials.gov/ct2/show/study/NCT01368588](https://clinicaltrials.gov/ct2/show/study/NCT01368588)