

TYPE OF CANCER: Prostate Cancer
TYPE OF TRIAL: Phase III
TRIAL SPONSOR: RTOG

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STUDY SUMMARY

A Phase III Trial of Short Term Androgen Deprivation with Pelvic Lymph Node or Prostate Bed only Radiotherapy (SPORT) in Prostate Cancer Patients with a Rising PSA after Radical Prostatectomy

TREATMENT OVERVIEW

- There are 3 treatment groups in this study:
 - Patients who receive radiation therapy to the prostate bed only;
 - Patients who receive hormone therapy for 4 to 6 months plus radiation therapy to the prostate bed;
 - Patients who receive hormone therapy for 4 to 6 months plus radiation therapy to the prostate bed and to the pelvic lymph nodes
- Patients will be randomized to one of the 3 treatment groups

PRE-TREATMENT ASSESSMENTS

- Prostate biopsy with Gleason Score
- History and physical
- Performance Status
- CT or MRI of abdomen and pelvis
- Bone Scan
- Digital Rectal Exam
- Hematology
- Biochemistry
- PSA
- Testosterone
- CT-sim with urethrogram or MRI-sim
- Tissue for central review

ENTRANCE CRITERIA FOR PARTICIPATION IN TRIAL

INCLUSION CRITERIA

- Adenocarcinoma of the prostate treated primarily with radical prostatectomy, pathologically proven to be lymph node negative by pelvic lymphadenectomy (N0) or lymph node status pathologically unknown (undissected pelvic lymph nodes [Nx]), i.e. lymph node dissection is not required

- Any type of radical prostatectomy will be permitted, including retropubic, perineal, laparoscopic or robotically assisted. If performed, the number of lymph nodes removed per side of the pelvis and the extent of the pelvic lymph node dissection (obturator vs. extended lymph node dissection) should be noted.
- A post-radical prostatectomy entry PSA of ≥ 0.2 and < 2.0 ng/mL at least 6 weeks after prostatectomy and within 30 days of registration
- One of the following pathologic classifications:
 - T3N0/Nx disease; or
 - T2N0/Nx disease with positive prostatectomy margin and/or positive prostatic fossa or urethral-vesical anastomosis biopsies
- Prostatectomy Gleason score of 8 or less
- PSA doubling time of > 6 months prior to registration (see Appendix VIII for PSA Doubling Time Worksheet)
- Zubrod Performance Status of 0-1
- Age ≥ 18
- A digital rectal exam within 30 days prior to registration
- No distant metastases, based upon the following minimum diagnostic workup:
 - History/physical examination within 8 weeks prior to registration;
 - A CT scan (with contrast if renal function is acceptable) or MRI of the abdomen and pelvis within 90 days prior to registration;
 - Bone scan within 90 days prior to registration; if the bone scan is suspicious, a plain x-ray and/or MRI must be obtained to rule out metastasis.
- Adequate bone marrow function, within 90 days prior to registration, defined as follows:
 - Platelets $\geq 100,000$ cells/mm³ based upon CBC;
 - Hemoglobin ≥ 12.0 g/dl based upon CBC (Note: The use of transfusion or other intervention to achieve Hgb ≥ 12.0 g/dl is acceptable).
- AST or ALT < 2 x the upper limit of normal within 90 days prior to registration
- Serum total testosterone within 90 days prior to registration
- Patients must sign a study-specific informed consent prior to study entry

EXCLUSION CRITERIA

- A palpable prostatic fossa abnormality/mass suggestive of recurrence, unless shown by biopsy under ultrasound guidance not to contain cancer
- N1 patients are ineligible, as are those with pelvic lymph node enlargement ≥ 1.5 cm in greatest dimension by CT scan or MRI of the pelvis, unless the enlarged lymph node is sampled and is negative
- Androgen deprivation therapy started prior to prostatectomy for > 6 months duration
- Androgen deprivation therapy started after prostatectomy and prior to registration

- Prior pelvic radiotherapy
- Prior invasive malignancy (except non-melanomatous skin cancer) unless disease free for a minimum of 5 years (for example, carcinoma in situ of the oral cavity is permissible)
- PSA doubling time of ≤ 6 months
- Severe, active co-morbidity, defined as follows:
 - History of inflammatory bowel disease
 - History of hepatitis B or C; Blood tests are not required to determine if the patient has had hepatitis B or C, unless the patient reports a history of it.
 - Unstable angina and/or congestive heart failure requiring hospitalization within the last 6 months
 - Transmural myocardial infarction within the last 6 months
 - Acute bacterial or fungal infection requiring intravenous antibiotics at the time of registration
 - Chronic Obstructive Pulmonary Disease exacerbation or other respiratory illness requiring hospitalization or precluding study therapy at the time of registration
 - Hepatic insufficiency resulting in clinical jaundice and/or coagulation defects; AST or ALT are required (see Section 3.1.11); note, however, that laboratory tests for coagulation parameters are not required for entry into this protocol
 - Acquired Immune Deficiency Syndrome (AIDS) based upon current CDC definition; Note, however, that HIV testing is not required for entry into this protocol. The need to exclude patients with AIDS from this protocol is necessary because the treatments involved in this protocol may result in increased toxicity and immunosuppression.
- Prior allergic reaction to the study drug(s) involved in this protocol