

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

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STUDY SUMMARY

A Phase III Protocol of Androgen Suppression (AS) and 3DCRT/IMRT vs AS and 3DCRT/IMRT by Chemotherapy With Docetaxel and Prednisone For Localized, High-Risk Prostate Cancer

TREATMENT OVERVIEW

- All patients will receive androgen suppression within 6 weeks after registration. Oral antiandrogen will be discontinued at the end of radiation therapy. LHRH agonist will continue for 24 months from initiation
- Radiation therapy will begin 8 weeks after the initiation of hormone treatment
- After radiation therapy, patients on arm 2 will also receive 6 cycles of docetaxel and prednisone

PRETREATMENT ASSESMENT

- Medical history
- Physical Examination
- Vital signs (height, weight)
- Bone scan
- CT pelvis and other lymph node assessment]
- Prostate Biopsy
- Hematology
- Chemistry
- Testosterone
- PSA
- Urine Pregnancy test

ENTRANCE CRITERIA FOR PARTICIPATION IN TRIAL

Inclusion Criteria

1 Histologically confirmed (within 180 days prior to registration) prostate cancer at high-risk for recurrence as determined by one of the following combinations:

Gleason Score		PSA		T-stage
≥9	and	≤ 150	and	Any
8	and	< 20	and	≥ T2
8	and	≥ 20-150	and	Any
7	and	≥ 20-150	and	Any

Histological diagnosis of index lesion for accrual must be performed within 180 days prior to registration. Patients may have had positive prostate cancer biopsies previously and undergone active surveillance. Dates and Gleason scores of previous positive biopsies, if any, must be available.

2 Clinically negative lymph nodes as established by imaging (pelvic CT or pelvic MR), 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 with positive lymph nodes by capromab pendetide (ProstaScint) scans are eligible provided a corresponding lymph node identified by CT or MR imaging is ≤ 1.5 cm.

3 No distant metastases, based upon the following minimum diagnostic work-up:

- History/physical examination (including weight) within 8 weeks prior to registration
- Bone scan within 90 days prior to registration. Equivocal bone scan findings are allowed if plain films are negative for metastasis.

4 Zubrod performance status 0-1

5 Age ≥ 18

6 CBC/differential obtained within 2 weeks prior to registration on study, with adequate bone marrow function defined as follows:

- Absolute neutrophil count (ANC) ≥ 1,800 cells/mm³
- Platelets ≥ 100,000 cells/mm³
- Hemoglobin ≥ 8.0 g/dl (Note: The use of transfusion or other intervention to achieve Hgb ≥ 8.0 g/dl is acceptable)

7 Pretreatment serum PSA, obtained prior to any LHRH or antiandrogen therapy, within 180 days of randomization.

8 ALT, AST, and total bilirubin within 1.5X institutional upper normal limits; and alkaline phosphatase within 2.5X institutional upper normal limits, obtained within 8 weeks prior to registration.

9 Medical oncology consultation prior to registration.

10 Prior 5-alpha reductase inhibitor (for example, finasteride) for prostatic hypertrophy is allowed if discontinued at least 60 days prior to registration.

11 Prior testosterone administration is allowed if last administered at least 90 days prior to registration.

12 Prior pharmacologic androgen ablation for prostate cancer is allowed only if the onset of androgen ablation is ≤ 50 days prior to the date of registration.

13 Patient must sign study specific informed consent prior to study entry.

14 Men of child-producing potential must be willing to consent to use effective contraception while on treatment and for at least 3 months afterwards.

Exclusion Criteria

1 PSA > 150

2 Evidence of M1 metastatic disease

3 Pathologically positive lymph nodes or nodes > 1.5 cm on imaging

4 Prior radical prostatectomy, cryosurgery for prostate cancer, or bilateral orchiectomy for any reason

5 Prior invasive malignancy (except non-melanomatous skin cancer) unless disease free for a minimum of 3 years (For example, carcinoma in situ of the oral cavity or bladder are permissible)

6 Prior systemic chemotherapy for the study cancer; note that prior chemotherapy for a different cancer is allowable. See Section 3.2.5.

7 Prior radiotherapy, including brachytherapy, to the region of the study cancer that would result in overlap of radiation therapy fields

8 Severe, active co-morbidity, defined as follows:

- 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

- 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 be significantly immunosuppressive.

9 Prior allergic reaction to the drugs involved in this protocol or to other drugs formulated with polysorbate 80.

10 Existing peripheral neuropathy \geq grade 2.

11 Study entry PSA obtained during the following time frames: (1) 10-day period following prostate biopsy; (2) following initiation of hormonal therapy; (3) within 30 days after discontinuation of finasteride; (4) within 90 days after discontinuation of dutasteride.