

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

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STUDY SUMMARY

A Phase III Study Comparing Combined External Beam Radiation and Transperineal Interstitial Permanent Brachytherapy With Brachytherapy Alone for Selected Patients With Intermediate Risk Prostatic Carcinoma

TREATMENT OVERVIEW

Treatment consists of two arms. If you are randomized to arm 1 you will receive external radiation therapy followed by brachytherapy (internal radiation) to your prostate. Treatment arm 2 consists of Brachytherapy alone. Both treatments will be given on an outpatient basis.

PRE-TREATMENT ASSESSMENTS

- History and physical (to include tumor measurements and DRE)
- Zubrod performance status.
- Histological evaluation of prostate biopsy with assignment of a Gleason score to the biopsy material.
- **LABORATORY EVALUATIONS** - CBC, platelets, BUN, creatinine, free prostate specific antigen (PSA) if available, and PSA. PSA must be done:
 - Within 60 days prior to study entry and prior to prostate biopsy or
 - Within 60 days prior to study entry and at least 10 days after prostate biopsy or
 - For patients receiving neoadjuvant hormone therapy, PSA must be done within 60 days prior to initiation of hormones.

Note: PSA obtained > 60 days prior to study entry and/or within 10 days following prostate biopsy must not be used for study entry PSA (for those patients not on hormones).

- Transrectal ultrasound volume study of the prostate prior to the planned external beam radiation therapy.

- Flexible cystoscopy, if advised by the urologist, may be performed to check for urethral strictures.
- Lymph node evaluation must be performed by at least one of the following: CT or MRI of pelvis, or exploratory laparotomy or laparoscopy with lymph node biopsy
- Completion of study specific questionnaires (EPIC, EQ5D, AUA Symptom Score) completed by the patient
- Utilization of Sexual Medications/Devices completed by the patient.

ENTRANCE CRITERIA FOR PARTICIPATION IN TRIAL

Conditions for Patient Eligibility:

1. Histologically confirmed adenocarcinoma of the prostate, clinical stage T1c, N0, M0. Lymph node evaluation by CT, MRI, or node dissection is required.
2. Zubrod performance status 0-1.
3. Patient must be ≥ 18 years of age.
4. Patients with intermediate risk prostate cancer as determined by one of the following combinations: Gleason < 7 , PSA must be 10-20; Gleason 7, PSA must be < 10 .
5. Prostate specific antigen (PSA) prior to study entry (and prior to any hormone treatment if given) must be ≤ 20 ng/ml.
6. Neoadjuvant hormonal therapy beginning 2-6 months prior to registration is acceptable. The use of 5-alpha reductase inhibitors (for example, finasteride) is allowed prior to registration but should be discontinued before registration.
7. Prostate volumes by TRUS ≤ 60 cc.
8. AUA voiding symptom scores ≤ 15 (alpha blockers allowed); this is completed by the patient.
9. Patients must sign a study-specific informed consent form prior to study entry.

Conditions for Patient Ineligibility

1. Stage $< T1c$, T2c, T3 or T4 disease
2. Lymph node involvement (N1).
3. Evidence of distant metastases (M1).
4. Radical surgery for carcinoma of the prostate, prior pelvic radiation, prior chemotherapy for prostate cancer, prior TURP, prior cryosurgery, TUNA, TUMT of the prostate.

- 5.** Previous hormonal therapy beginning < 2 months or > 6 months prior to registration. The use of hormones should not be a planned component of therapy.
- 6.** Previous or concurrent cancers other than basal, in situ, or squamous cell skin cancers unless disease-free for ≥ 5 years.
- 7.** Major medical or psychiatric illness, which in the investigator's opinion, would prevent completion of treatment and would interfere with follow-up.
- 8.** Hip prosthesis.

