

RTOG 0626

**A PHASE II STUDY
USING PROTON BEAM RADIATION THERAPY
WITH ANDROGEN DEPRIVATION
FOR
LOCALLY ADVANCED ADENOCARCINOMA
OF THE PROSTATE**

Locally Advanced Prostate Cancer

- ~15% of cases diagnosed in US
- Local treatment is external radiation
- High rates of local failure in the PSA era at doses < 70 Gy
 - Local failures in early stage prostate cancer patients treated with I-125 implantation have been associated with a higher rate of distant metastases

Locally Advanced Prostate Cancer

- Adjuvant hormonal therapy
 - Laverdiere et al
 - 3 months of neoadjuvant Rx yielded a 50% reduction in the positive rebiopsy rate at 2 years
 - RTOG 8610
 - Local control and biochemical DFS advantage has been seen out to 8 years with 4 month course of neoadjuvant goserelin vs. conventional radiation

Radiation Dose in Prostate Cancer

- Pollack et al (MD Anderson)
 - Advantage to high dose conformal 79Gy vs. 70Gy with intermediate risk T1-3 disease, especially in patients with PSA > 10ng/ml
- PROG 9509 (MGH/Loma Linda)
 - 393 patients with low/intermediate risk T1-2 tumors randomized to 79.2 GyE vs. 70.2 GyE
 - Boost with protons
 - Biochemical RFS 80.4% vs. 61.4%
- NKI (Holland)
 - Improved outcome with 78 Gy vs. 68 Gy

Eligibility

- Adenocarcinoma of the prostate
 - Stages T1c-T3, N0, M0 and Gleason ≥ 5
 - For T1c-T2b patients, pre-hormone therapy PSA values must be >15 ng/ml and < 50 ng/ml
 - For T2c-T3 patients, any PSA < 50 ng/ml for Gleason Score 8-10.

85 Patients

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- Six months total androgen blockade starting 4 months prior to radiation.
- Androgen deprivation to continue for a total of 2 years for men with Gleason Score 8-10 or PSA >30 ng/ml

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Initial Phase (protons)

GTV1 = CTV1 = Prostate alone

Dose: 19.8 GyE; 11 daily fractions of 1.8 GyE

Second Phase (protons)

Target: Prostate + proximal seminal vesicles

CTV2 = GTV2 + 0.5 cm

Dose: 18 GyE; 10 daily fractions of 1.8 GyE

Third Phase (photons)

Target: Prostate + seminal vesicles + regional nodes

CTV3 = GTV2 + 1.0 cm

Dose: 45 GyE; 25 daily fractions of 1.8 GyE

Total Dose to GTV: 82.8 GyE in 9 weeks

Objectives

- Primary
 - Assess the late severe Grade 3-4 morbidity of 82.8 Gy delivered using combined conformal photon/proton beam therapy to the prostate gland and surrounding tissues and androgen deprivation.

Objectives

- Secondary
 - Biochemical failure/local persistence
 - Prospective, patient-reported Quality of Life evaluation using validated instrument

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- First RTOG study where both photons and protons will be employed
 - Apart from the dose escalation, the treatment approach is standard
 - Opportunity to develop infrastructure for electronic data transfer for studies incorporating protons
 - Allows for experience within RTOG using a sensitive, new validated quality of life instrument in the rectal and bladder domains that we anticipate might be incorporated into subsequent trials