

**PROSPECTIVE EVALUATION OF HYPOFRACTIONATED
STEREOTACTIC BODY RADIOTHERAPY AS TREATMENT FOR
HIGH RISK PROSTATE CANCER**

**New Jersey Cyberknife
Barnabas Health
J. Philip Citta Regional Cancer Center
Community Medical Center**

Principal Investigator: David J. D'Ambrosio, MD
Co-Principal Investigator: Rajesh Iyer, MD
Co-Investigator Deborah Moriarty, RN, OCN

Adapted from the University of Pittsburgh Protocol for treatment of Low and Intermediate risk prostate cancer

SCHEMA

Title

PROSPECTIVE EVALUATION OF HYPOFRACTIONATED STEREOTACTIC BODY RADIOTHERAPY AS TREATMENT FOR HIGH RISK PROSTATE CANCER

Objectives

The *primary* objectives of this study are:

1. To determine the rates of acute and late grade 3 or higher gastrointestinal and genitourinary toxicity observed during an initial 24 month follow up.

The *secondary* objectives of this study are to:

To determine

1. the rate of local failure
2. rate of distant failure
3. rate of biochemical failure using nadir+2 definition
4. rate of disease-specific survival
5. overall survival
6. quality of life (QOL) in generic and organ-specific domains

Patient population

In order to be eligible for this study, patients will have a histologically confirmed adenocarcinoma of the prostate which is a clinical stage T1b-T3b, Nx-0 and Mx-0. The following combinations will be allowed:

- Gleason score 8-10 OR PSA >20 OR T3a-b

INELIGIBILITY

Any evidence on exam or radiographic imaging of local or distant metastatic disease including lymph nodes.

All patients will have an ECOG Performance Status of 0-2 and have had no prior prostate radiation or definitive therapy.

Treatments administered

SBRT:

Patients will receive 36.25 Gy in 5 fractions (7.25 Gy/fx) delivered over a 2-week period.

Androgen Deprivation

Men will receive a minimum of two years of androgen deprivation at the discretion of the treating physicians