

**PROSPECTIVE EVALUATION OF HYPOFRACTIONATED
STEREOTACTIC BODY RADIOTHERAPY FOR LOW AND
INTERMEDIATE RISK PROSTATE CANCER (09-031)**

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PROTOCOL SUMMARY

Title

A Prospective Evaluation of Hypofractionated Stereotactic Body Radiotherapy (SBRT) for Low and Intermediate Risk Prostate Cancer

Objectives

The *primary* objectives of this study are:

1. To determine, in both low-risk and intermediate-risk cohorts, the rates of acute and late grade 3 or higher gastrointestinal and genitourinary toxicity observed during an initial 24 month follow up.
2. To estimate the rate of biochemical Disease-Free Survival (bDFS), Phoenix and ASTRO definitions, at 2 years following hypofractionated SBRT for low and intermediate risk prostate cancer.

The *secondary* objectives of this study are to:

To determine

1. the rate of local failure
2. rate of distant failure
3. rate of disease-free survival
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-T2b, Nx-0 and Mx-0. The following combinations will be allowed:

- Gleason score 2-6 and PSA \leq 20
- Gleason score 7 and PSA \leq 10

All patients will have an ECOG Performance Status of 0-1 and have had no prior prostate radiation or definitive therapy.

Number of patients

111

Study design and methodology

This is a phase II study.