

FAST FACTS

NRG GU013: THE PHASE III 'HIGH FIVE TRIAL' FIVE FRACTION RADIATION FOR HIGH-RISK PROSTATE CANCER

ELIGIBILITY CRITERIA

Inclusion Criteria

1.1 Documentation of Disease

Pathologically (histologically or cytologically) proven diagnosis of adenocarcinoma of prostate cancer.

1.2. Definition of Disease

1. High-risk disease defined as having at least one or more of the following:

- cT3a-T3b by digital exam or imaging (AJCC 8th Ed.) Note: cT4 by imaging or on digital rectal exam is not allowed.
- The patient's PSA value >20 ng/mL prior to starting ADT Note: Patients taking a 5-alpha reductase inhibitor (ex finasteride or dutasteride) are eligible The baseline PSA value should be doubled for PSAs taken while on 5-alpha reductase inhibitors.
- Gleason Score of 8-10
- Pelvic node positive by conventional imaging with a short axis of at least 1.0 cm

2. Prostate gland volume less than 100 cc prior to initiation of ADT as reported at time of biopsy or by separate measure with ultrasound or other imaging modalities including MRI or CT scan.

3. No definitive clinical or radiologic evidence of metastatic disease outside of the pelvic nodes (M1a, M1b or M1c) on conventional imaging (i.e. bone scan, CT scan, MRI); Negative PSMA PET is an acceptable substitute.

1.3 Age \geq 18

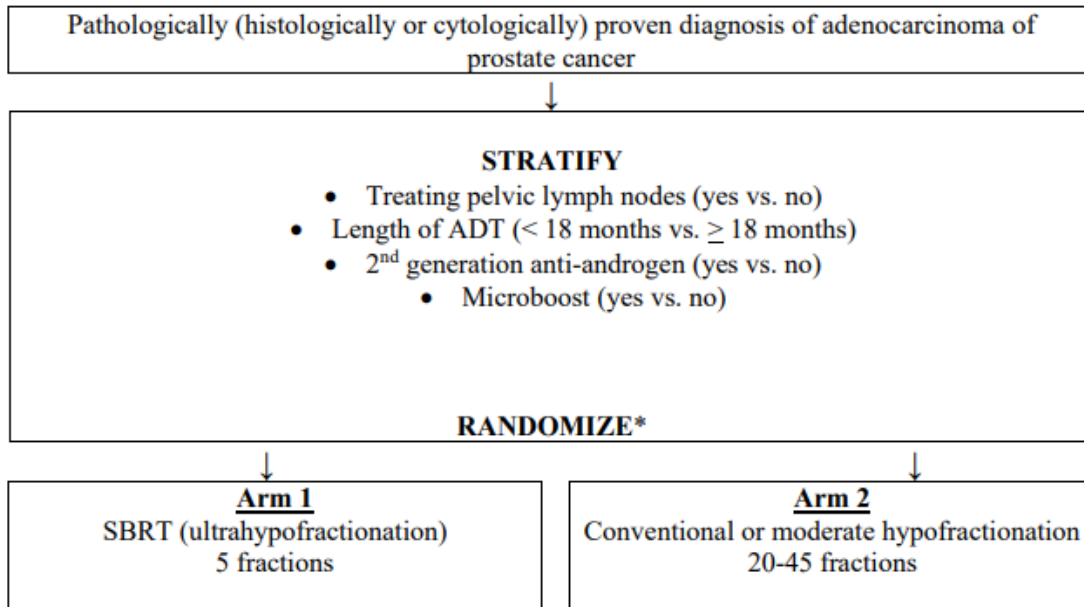
1.4 ECOG Performance Status of 0-2

1.5 Prior Treatment

- No prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields;
- No prior radical prostatectomy;
- Prior pharmacologic androgen ablation for prostate cancer is allowed only if the onset of androgen ablation (both LHRH agonist and oral anti-androgen) is \leq 185 days prior to registration; Please note: PSA prior to the start of any ADT will be used to define disease in 1.2.

1.6 Co-Enrollment with NRG-GU009 (ONLY Applies to Patients enrolled in NRRGU009) Patients enrolled in NRG-GU009 must be enrolled in NRG-GU013 prior to radiation therapy treatment planning and start of radiation therapy. For details, see Section 5.4.

**NRG-GU013
SCHEMA**



*Randomization is 1:1