NRG ONCOLOGY

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IROC™ IMAGING AND RADIATION ONCOLOGY CORE

Global Leaders in Clinical Trial Quality Assurance

NRG-GU005

PHASE III IGRT AND SBRT VS IGRT AND HYPOFRACTIONATED IMRT FOR LOCALIZED INTERMEDIATE RISK PROSTATE CANCER

Stratification

- Risk Group
- Use of rectal manipulation

Randomization

- **Arm 1: Hypofractionated IMRT**
  70 Gy/28 fxs/2.5 Gy per fraction

- **Arm 2: SBRT**
  36.25 Gy/5 fxs/7.25 Gy per fraction

RT Credentialing Requirements

- Update the IROC Houston Facility Questionnaire (FQ)
- Complete Credentialing Status Inquiry (CSI) Form
- Complete IMRT H&N Phantom Irradiation
- Complete IGRT Credentialing for soft tissue IGRT
- Sites that previously successfully irradiated the phantom may not need to repeat a phantom irradiation
- Sites with both Linac and Cyberknife units, the Cyberknife unit must be credentialed for each machine type due to possibility case randomized to SBRT

Refer to Section 8.3 for futher details

Mandatory MRI Imaging

- Diagnostic/Staging MRI within 90 days for eligibility evaluation, to exclude patients with definitive T3 disease.
- A dedicated planning (simulation) MRI is also recommended to assist target delineation.
- MRI simulation imaging: Integrating MRI in the radiotherapy planning process is recommended to improve accuracy of anatomic delineation of prostatic and adjacent structures for treatment planning. It is also recommended in order to incorporate information on the extent and distribution of disease (such as gross disease abutting the SV) in the treatment plan.
- MRI is required for GTV, CTV, and urethra definition and must be fused into the planning CT scan for CT-based planning.

Refer to Section 4.1 for further details

Radiation Therapy

Arm 1: Hypofractionated IMRT

- 70 Gy/28 fxs/2.5 Gy per fraction
- All fields treated once daily
- 5 fractions per week
- Completed in <32 business days

Arm 2: SBRT

- 36.25 Gy/5 fxs/7.25 Gy per fraction
- 2-3 fractions per week/at least every other day
- Completed in <12 business days

Pre-Treatment RT Review Required for:

- First Arm 2 patient enrolled from each institution PRIOR TO DELIVERY of radiation treatment

Post-Treatment RT Reviews:

- After an institution has passed the Pre-Treatment review of the first Arm 2 patient enrolled, review of all other Arm 2 cases and all Arm 1 cases will be ongoing and performed remotely.

Refer to Section 5.2 for further details

Digital Data Submission to TRIAD

- DICOM Staging MR
- DICOM Planning MR, when applicable
  MP-RAGE, TSE, axial T2/FLAIR sequences, and gadolinium contrast-enhanced three-dimensional SPGR
- DICOM Registration, when applicable
- DICOM Treatment Planning CT Data Set
- DICOM Treatment Planning RT Structure
- DICOM Treatment Planning RT Dose
- DICOM Treatment Planning RT Plan

TRIAD submission time point = RT DIGITAL PLAN

Arm 1 Cases & Arm 2 Cases*

**after 1st Pre-Treatment Review Case*

Due within 1 week of the start of RT

Staging MRI TRIAD submission time point = BASELINE

More information on the next page

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NRG-GU005 MRI Guidelines in accordance with PIRADSv2

MRI sequences to be completed in accordance with PIRADSv2 include the following:

T1 Weighted Items (T1WI)

Axial T1W images of the prostate:

- Spin echo or gradient echo sequences
- With fat suppression
- Locations should be the same as those used for DWI (Diffusion Weighted Imaging) and DCE (Dynamic Contrast Enhanced) imaging

Lower spatial resolution compared to T2W may be used to decrease acquisition time or increase anatomic coverage.

T2 Weighted Items (T2WI)

In all three planes (axial, sagittal, and coronal). While all three planes are desirable, cases with only two planes, at least one being axial, will not be excluded from the study:

- 2D
- Slice thickness: 3mm, no gap. FOV: 12-20 cm (to encompass the entire prostate gland and seminal vesicles)
- In plane dimension: ≤0.7mm (phase) x ≤0.4mm (frequency)
- Locations should be the same as those used for DWI and DCE

Multi-planar (axial, coronal, and sagittal) T2W images are usually obtained with 2D RARE (rapid acquisition with relaxation enhancement) pulse sequences, more commonly known as fast-spin echo (FSE) or turbo-spin-echo (TSE).

To avoid blurring, excessive echo train lengths should be avoided.

Axial DWI - must include a b value of >1400

- Free-breathing spin echo EPI with spectral fat sat recommended
- TE: ≤90msec; TR: ≥3000msec
- Slice thickness: ≤3mm, no gap
- FOV: 16-22cm
- In plane dimension: ≤2.5mm phase and frequency
- Locations should match or be similar to those used for T2W and DCE

Axial pre and post DCE-MRI series

DCE is generally carried out for several minutes to assess the enhancement characteristics. To detect early enhancing lesions in comparison to background prostatic tissue, temporal resolution should be <10 seconds and preferably <7 seconds per acquisition in order to depict focal early enhancement. Fat suppression and/or subtractions are recommended.

- 3D GRE, although either a 2D or 3D T1 gradient echo (GRE) sequence may be used; 3D is preferred.
- TR/TE : <100msec/<5msec
- Slice Thickness: 3mm, no gap.
- FOV: encompass the entire prostate gland and seminal vesicles
- In plane dimension: <2mm x <2mm
- Locations should be the same as those used for DWI and T2W

Submit all images via TRIAD

Contact Information

For MRI questions, contact Lead Imaging Technologist, Cyndi Price at cprice@acr.org or (215) 940-8863

For RT questions, contact GU Disease Site Dosimetrist, Joanne Hunter at jhunter@acr.org or (215) 574-3222