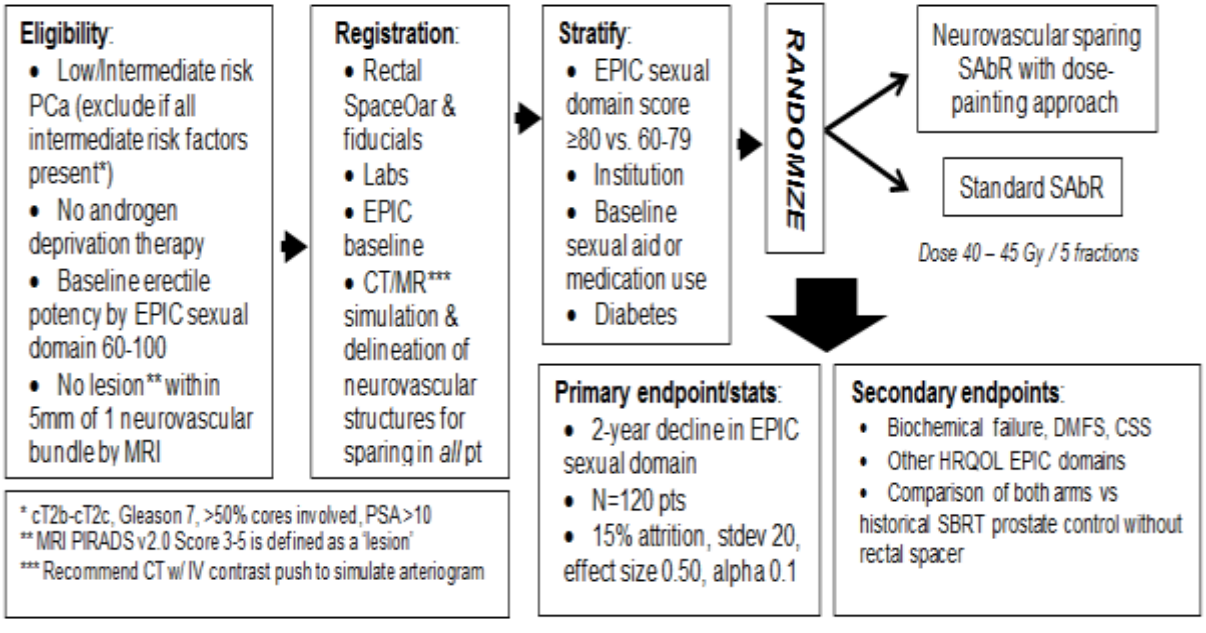
PTEN-C

Trial Schema



Patient talking points

- While achieving high survival rates, standard surgery or radiation for localized prostate cancer results in erectile dysfunction (ED) or loss of sexual function in 50% or more of men
- Nerves and blood vessels supplying the penis surround the prostate and are damaged during radiation or surgery
- In this study, we are testing the ability of SAbR, a highly focused radiation technique, with detailed MR imaging and a rectal spacer hydrogel (SpaceOAR®, Augmenix) to spare these neurovascular elements and hopefully reduce ED
- If you choose to participate, you will be randomly offered either standard SAbR therapy or SAbR with reduced dose to neurovascular structures and followed with quality of life questionnaires.

P TEN-C

A phase II randomized controlled trial of stereotactic ablative body radiotherapy (SAbR) with or without neurovascular sparing for erectile function preservation in localized prostate cancer (6/2018 V5)

Eligibility Summary (see protocol for full criteria)

- Age ≥ 18 years & ECOG/Zubrod 0-2
- AJCC 7th cT1-T2N0M0 (DRE optional)
- Gleason 6-7 (template bx recommended. If only fusion bx, all PIRADS v2 score 4-5 must be sampled)
- Serum PSA ≤20 ng/mL
- Baseline AUA symptom score ≤19
- **EPIC sexual domain composite score 60-100 (Key inclusion)**
- mpMRI prostate required with confirmed >5mm minimum distance from at least once side's neurovascular bundle to nearest lesion (defined PIRADS v2 score 3-5). See example image.
- Gland size ≤80 gm (consider cytoreduction for >60gm size)
- No androgen deprivation therapy
- No significant penile malformation or implant
- Men must not require ED medication or device to achieve erections sufficient for intercourse.
- No prior TURP
- Testosterone >280 ng/dL
- MRI equivocal ECE opposite to spared side allowed at investigator discretion
- Pts may not have all 3 int risk features (PSA >10, cT2b-c, Gleason 7) AND ≥50% template cores involved