

CAPTAIN

Inclusion & Exclusion Criteria

CAPTAIN is a randomized controlled trial (RCT) comparing the efficacy and safety of two different treatment options, Radical Prostatectomy (RP) and the TULSA Procedure, for men with intermediate-risk prostate cancer.

The main purpose of CAPTAIN is to compare specific outcomes for each treatment, including:

1. Preservation of quality-of-life functions (urinary, bowel, and sexual).
2. Treatment effectiveness (undergoing additional prostate cancer treatment, the spread of prostate cancer, or death caused by prostate cancer).

Inclusion Criteria

Below is a list of inclusion criteria, that would allow a patient to participate in the CAPTAIN trial.

- | | |
|---|---|
| <input type="checkbox"/> Male | <input type="checkbox"/> Treatment-naïve |
| <input type="checkbox"/> Age 40-80 years, with >10 year life expectancy | <input type="checkbox"/> PSA ≤20ng/mL within last 3 months |
| <input type="checkbox"/> Stage ≤cT2c, N0, M0 | <input type="checkbox"/> ISUP Grade Group 2 or 3 disease on TRUS-guided biopsy or in-bore biopsy |
| <input type="checkbox"/> Biopsy-confirmed, NCCN (favorable and unfavorable) intermediate-risk prostate acquired within last 12 months | <input type="checkbox"/> Planned ablation volume is < 3 cm axial radius from urethra on mpMRI acquired within last 6 months |

Exclusion Criteria

*Below is a list of exclusion criteria, that would **not** allow a patient to participate in the CAPTAIN trial.*

- | | |
|---|--|
| <input type="checkbox"/> Inability to undergo MRI or general anesthesia | <input type="checkbox"/> Inability or unwillingness to provide informed consent |
| <input type="checkbox"/> Suspected tumor is >30 mm from the prostatic urethra | <input type="checkbox"/> Patients who are otherwise not deemed candidates for radical prostatectomy |
| <input type="checkbox"/> Prostate calcifications is > 3 mm in maximum extent obstructing ablation of tumor | <input type="checkbox"/> Artificial urinary sphincter, penile implant, or intraprostatic implant |
| <input type="checkbox"/> Unresolved urinary tract infection or prostatitis | <input type="checkbox"/> History of anal or rectal fibrosis or stenosis, or urethral stenosis, or other abnormality challenging insertion of devices |
| <input type="checkbox"/> History of proctitis, bladder stones, hematuria, history of acute urinary retention, severe neurogenic bladder | |

For more information about the CAPTAIN trial, [CLICK HERE](#)