CAPTAIN

A Randomized Controlled Trial

A Comparison of the TULSA Procedure vs. Radical Prostatectomy in Participants with Localized Prostate Cancer

This study is sponsored by Profound Medical Inc.

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Understanding CAPTAIN

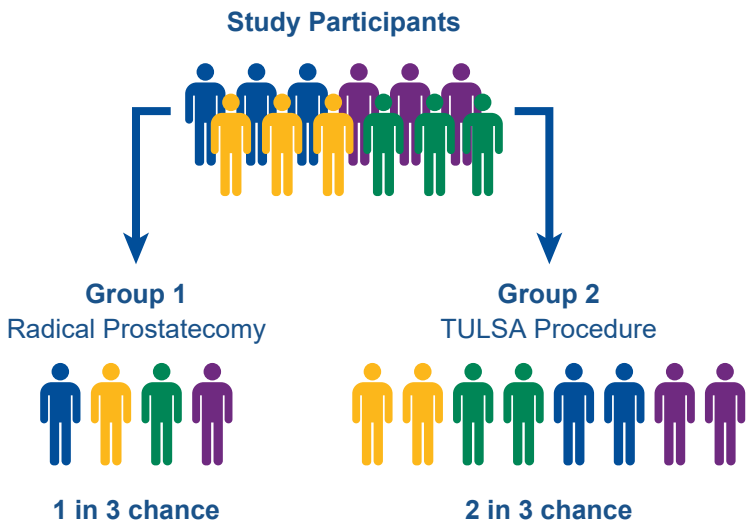
What is CAPTAIN?

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

What is a randomized controlled trial (RCT)?

If you agree to join the CAPTAIN RCT, the study team will use a computer algorithm to randomly assign you to either **Group 1** (Radical Prostatectomy) or **Group 2** (TULSA Procedure). You will have a 1 in 3 chance of getting a Radical Prostatectomy and a 2 in 3 chance of getting the TULSA Procedure.



What are the benefits?

The National Comprehensive Cancer Network[1] (NCCN) encourages patients to participate in clinical trials because they believe that the best management of any patient with cancer is in a clinical trial. You may benefit as a result of your participation in this study, and you will receive close monitoring of your prostate cancer. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

[1]nccn.org

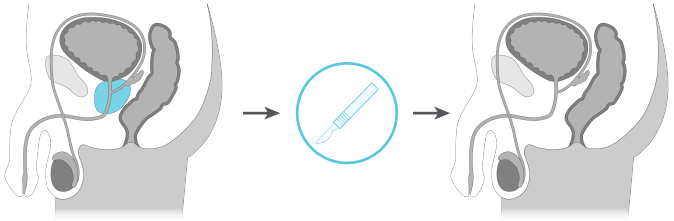
Participating in CAPTAIN

Am I eligible?

If you are between 45 and 80 years of age with intermediate-risk prostate cancer, your study physician will review the eligibility criteria with you to see if you can participate in the CAPTAIN trial. You will be assigned to either the Radical Prostatectomy group or the TULSA Procedure group if you qualify.

What is a Radical Prostatectomy (RP)?

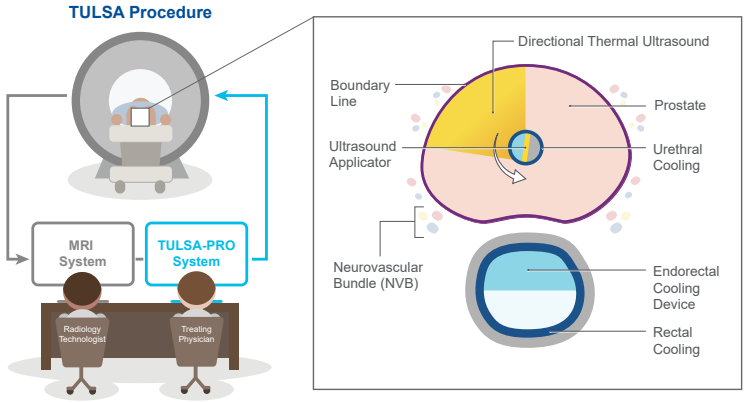
Radical Prostatectomy is a procedure that involves the surgical removal of your prostate and some tissue around it. For men with localized, intermediate-risk prostate cancer, RP is recommended to be a standard-of-care treatment[2] and has been proven in large randomized controlled trials to reduce the long-term risk of dying from prostate cancer.



[2]auanet.org

What is the TULSA Procedure?

The Transurethral Ultrasound Ablation (TULSA) Procedure uses directional thermal ultrasound to ablate (destroy) diseased prostate tissue. It has been demonstrated to be effective at ablating prostate tissue in men with localized, intermediate-risk prostate cancer. The TULSA Procedure is performed in a Magnetic Resonance Imaging (MRI) suite and uses the TULSA-PRO® system to ablate prostate tissue from the 'inside-out' (from inside the urethra heating outwards to the edge of the prostate). The TULSA Procedure is approved for use by the United State Food and Drug Administration (FDA) and Health Canada.



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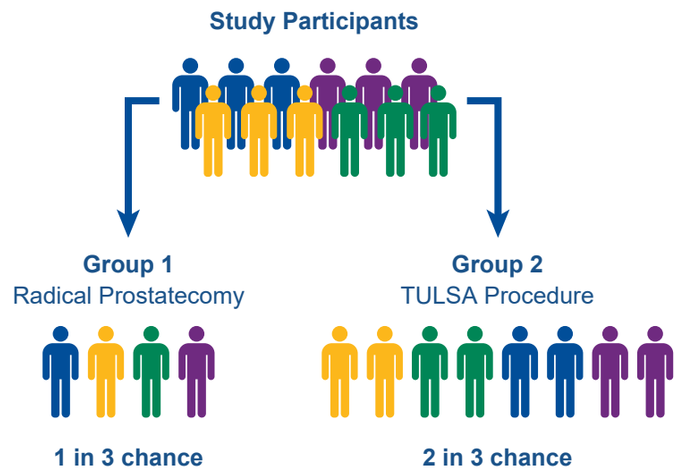

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[1]nccn.org

Patient Journey Map

Screening

Various tests, such as Magnetic Resonance Imaging (MRI), Biopsy, Prostate-Specific Antigen (PSA) test, CT scan (if necessary) and nuclear imaging (if necessary), will be conducted to determine whether you are approved to participate in the study.

Baseline

Once approved, your study physician will do a clinical exam before your treatment and compare these measurements to a clinical exam after your treatment.

Randomization

You will be randomly assigned to either undergo the TULSA Procedure or a Radical Prostatectomy.

Treatment Visit

You will undergo the treatment of your assigned group and will be discharged from the hospital accordingly. Regardless of which treatment you receive, patients will leave the hospital with a catheter inserted.

Catheter Removal

Your study physician will decide the appropriate time and place for your catheter to be removed.

Follow-Up Appointments

For every follow-up visit, you will need to answer questions about your quality-of-life, do a PSA test, tell your study physician about any side-effects you are experiencing and if you have undergone any other treatments for your prostate cancer.

Early Follow-Up Visits

Month: 1 3 6 9 12 18

Long-term Follow-Up Visits

Year: 2 3 4 5 6 7 8 9 10

Depending on which treatment you received, additional tests and different follow up assessments will be conducted during the **12th month,** and **2nd year** follow-up appointments. Your study physician will monitor your progress for the next 10 years. Certain visits may be done remotely. Contact your study physician for more information.

Common Questions

What will it cost me?

If you decide to participate in the study, your insurance may be billed for the Radical Prostatectomy or the TULSA Procedure, and you may have to pay a portion of the cost as an out-of-pocket co-pay. Please contact your study physician for more details on costs associated with the study.

Will I be compensated?

You will not be paid to take part in this study. However, you may be reimbursed for study-related expenses and compensated for your time in completing the required study questionnaires. Ask your study physician about reimbursements and compensation for participation.

Is my confidentiality maintained?

Only the information needed for the study will be collected. Your information will be de-identified, and you will be assigned a study ID number. Your information will be stored in a HIPAA compliant electronic database. Only aggregate results will be made public, and no information that can identify you will be shared.

What are the risks?

Common risks associated with both procedures may include the inability to get or maintain an erection, urine leakage, urinary tract infection, deep vein thrombosis, tightening of the bladder outlet and/or urethra requiring additional intervention, and potential worsening of urinary symptoms, including increased frequency and/or urgency and the need to urinate at night.

Some risks associated with a Radical Prostatectomy are blood loss requiring transfusion and damage to the rectum.

Some risks related to the TULSA Procedure are blood in the urine, urethral discharge, and urinary retention.

Some side effects may go away, and some may last longer or be perminent. Your study physician will review all these risks with you before you undergo treatment.

For more information, visit:

Site Address

Site Contact info

Site logo

www.clinicaltrials.gov/ct2/show/NCT05027477

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