CAPTAIN

A Randomized Controlled Trial

Customized Ablation of the Prostate with the TULSA Procedure Against radical prostatectomy treatment: a randomized controlled trial for localized prostate cancer

NCT05027477

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 treatment options, **Radical Prostatectomy (RP)** and the **TULSA Procedure**, for men with intermediate-risk prostate cancer.

Primary Objectives

1 To determine if the TULSA Procedure is superior to RP for safety by comparing the preservation of erectile potency & urinary continence at 1 year.

2 To determine if the TULSA Procedure is not inferior to RP for efficacy by comparing the rate of salvage treatment at 3 years.

Eligible Patient Population

NCCN intermediate-risk cancer, excluding Gleason score 3+3:

- Gleason Score 3+4 or 4+3
- PSA ≤ 20 ng/mL
- Clinical stage ≤T2c, with no histologic or radiologic evidence of extraprostatic disease

Treatment-naïve

Planned ablation volume <3.0 cm axial radius from urethra

Ability to undergo MRI, general anesthesia, and radical prostatectomy

No prostate calcifications >3 mm in maximum extent (subject to Sponsor review and approval)

For the complete inclusion/exclusion criteria, please refer to the CAPTAIN study protocol.

The Procedures

Radical Prostatectomy (RP)

Patients randomized to radical prostatectomy arm will receive radical prostatectomy performed as per standard clinical practice at your site, with no restriction on approach.

The TULSA Procedure

The Transurethral Ultrasound Ablation (TULSA) Procedure uses directional thermal ultrasound to ablate 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 cleared for use by the United States Food and Drug Administration (FDA) and Health Canada.

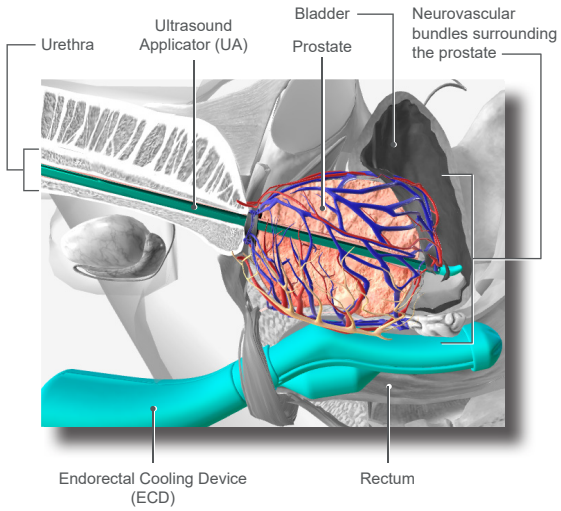

Figure 1. During the TULSA Procedure, the Ultrasound Applicator is inserted in the urethra, and the Endorectal Cooling Device is inserted into the rectum.

To watch a video about the TULSA Procedure

CLICK HERE

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Clinical Evidence

Urinary Incontinence (Pad-Free) [1-3]

	RP	TULSA-PRO
Year 1	4%-31%	0%-8%

Erectile Dysfunction

(Insufficient firmness for penetration) [2-5]

Baseline (pre-operative)	33%-35%	17%-30%
Year 1 (post-operative)	69%-95%	31%-37%

Rate of Salvage Treatment [6-9]

Year 3	11%-14%	13%

Study Support

The clinical science team at Profound Medical works closely with study sites to support patient recruitment and retention efforts. Initiatives include:

- support with identifying or establishing a compatible MRI facility to perform the TULSA procedure
- training on the TULSA procedure, and support in treatment planning and delivery
- patient education and facilitation of referral to study site
- educational videos on the study objectives, procedures, risks and benefits, and education on the TULSA procedure to streamline patient consultations
- physician engagement and educational events to broaden referral and sub-investigator networks
- engaging referral networks by facilitating geo-targeted peer-to-peer education
- ongoing communication to identify and help address bottlenecks to recruitment
- direct-to-patient marketing with study physician finder

Joining CAPTAIN

Why get involved?

Level 1 evidence comparing emerging modalities for prostate ablation with standard of care therapies is lacking. The TULSA Procedure may provide a safer treatment option than radical prostatectomy for men with prostate cancer if proven in a head-to-head comparison. The CAPTAIN RCT will provide game-changing evidence that may define a less invasive treatment option for men with intermediate-risk prostate cancer.

How to get involved?

1. Become a Study Site

CAPTAIN is currently enrolling both academic and private practice sites, and is expanding the network of study sites, sub-investigators, and referring physicians. Scan the QR code on the back to learn how to become a study site.

2. Refer Patients to a Study Site

Comprehensive Urology Medical Group
Kiarash Michel, MD

Genesis Healthcare
Pooya Banapour, MD

Johns Hopkins School of Medicine
Christian Pavlovich, MD

Lawson Health Research Institute, London Health Sciences Centre
Joseph Chin, MD

San Fernando Valley Urological Associates Medical Group
Ali-Reza Sharif-Afshar, MD

Sunnybrook Research Institute
Laurence Klotz, MD

The University of Texas Southwestern Medical Center
Xiaosong Meng, MD

The Urology Place
Naveen Kella, MD

Yale Cancer Center
Sandeep Arora, MD, Preston Sprenkle, MD

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9. van Son, M.J., Peters, M., Reddy, D, et al. Conventional radical versus focal treatment for localised prostate cancer: a propensity score weighted comparison of 6-year tumour control. Prostate Cancer Prostatic Dis 2021; 24:1120–1128.

To become a study site or to refer a patient for *CAPTAIN* click below.

CLICK HERE

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