

A randomized controlled trial  
assessing investigational Aquablation therapy  
against radical prostatectomy for the treatment  
of localized prostate cancer

**AQUABLATION**<sup>®</sup>  
THERAPY

RESEARCH FOR MEN WITH LOCALIZED PROSTATE CANCER

Caution: Investigational device. Limited by Federal (or United States) law to investigational use only.

Patient Supplemental Information for the WATER IV PCa study.

## About the Study

**WATER IV Prostate Cancer (PCa) is a clinical study comparing investigational Aquablation<sup>®</sup> therapy and radical prostatectomy for the treatment of localized prostate cancer.**

The study will evaluate and compare the safety and efficacy of Aquablation therapy and radical prostatectomy for men with Grade Group (GG) 1 to 3 localized prostate cancer. Aquablation therapy is an image-guided, minimally invasive surgery that aims to resect (remove) diagnosed cancer and most of the prostate using a robotically-controlled waterjet. Radical prostatectomy is a traditional surgery that removes the entire prostate along with some surrounding tissue. A surgical robot is often used to perform the radical prostatectomy surgery.

The WATER IV PCa study will include men who are candidates for, or have already selected, surgery for their prostate cancer treatment.

## What is Prostate Cancer?

Prostate cancer is one of the most common types of cancer affecting 1 in 8 men according to both the American Cancer Society and Prostate Cancer UK.<sup>1,2</sup> Prostate cancer is the abnormal growth of prostate cells that may spread to other parts of the body if not treated.

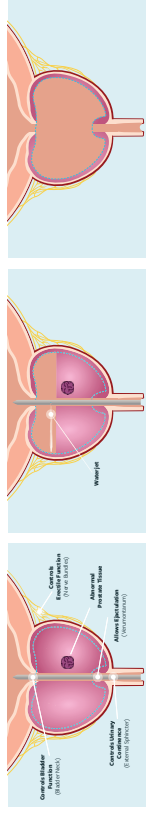
## What are the Treatment Options in this Study?

**There are two treatment options for the WATER IV PCa study: Aquablation therapy and radical prostatectomy.**

### Aquablation therapy

An advanced, minimally invasive surgical treatment that uses image guidance, robotics, and a heat-free waterjet to remove prostate tissue.

- The surgeon accesses the prostate through the urethra and uses ultrasound imaging to visualize the entire prostate.
- For each patient, the treatment is planned by a surgeon based on their individual anatomy. Tissue for both resection and preservation is identified. Surgeons take care to avoid treatment too close to nearby sensitive structures including those responsible for sexual and urinary function.
- The waterjet then follows the treatment plan and precisely resects the identified prostate tissue.



### Radical prostatectomy

A surgical approach that accesses the prostate through one or several incisions in the abdomen.

- Radical prostatectomies can be performed in one of three ways:
  - Open – single incision to access the prostate directly
  - Laparoscopic – multiple incisions to access the prostate using laparoscopic instruments
  - Robotic – multiple abdominal incisions to access the prostate using instruments on a surgical robot
- The surgeon removes the prostate and surrounding anatomy such as the seminal vesicles and lymph nodes, if needed.

## Who is a Candidate for the WATER IV PCa Study?

### You're a candidate if you are a biological male with Grade Group 1-3 localized prostate cancer

#### Grade Groups:

Grade groups indicate how different cancer cells look compared to normal prostate cells. Doctors perform a prostate biopsy to remove a small piece of prostate tissue to look at under a microscope. Based on how the cancer cells look, doctors assign a grade group (GG) from 1 (GG 1) to 5 (GG 5). The aggressiveness of the cancer is related to the cells' appearance with GG 1 being the least likely to grow and spread and GG 5 the most likely.

Sometimes a different grading system is used and a "Gleason score" from 6-10 is assigned rather than a grade group. This system is named after Dr. Gleason who came up with the scoring system.

A diagnosis of GG1-3 prostate cancer is one of the requirements to participate in the WATER IV PCa study.

#### Localized Cancer:

As part of a prostate cancer diagnosis, doctors "stage" the cancer. Staging prostate cancer is figuring out how much of the prostate contains cancer and if it has spread to other parts of the body. A tumor (T) score from 1-4 is assigned. If the prostate cancer is stage T1 or T2, the cancer is localized which means it is only inside the prostate. Stage T3 and T4 indicate the cancer has spread beyond the prostate.

Having localized disease, that is T1 or T2, is another requirement to participate in the WATER IV PCa study.

## See if you're a potential candidate:

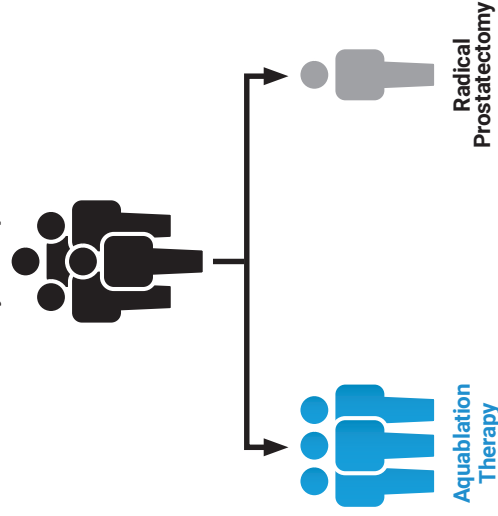
This table outlines candidacy for the WATER IV PCa study based on Grade Group and Tumor Stage.

Cancer Characteristic	Potential Candidate for WATER IV PCa
<b>GRADE GROUP</b>	
GG 1 (Gleason score 6)	Yes
GG 2 (Gleason score 7(3+4))	Yes
GG 3 (Gleason score 7(4+3))	Yes
GG 4 or 5	No
<b>TUMOR STAGE</b>	
T1a, b, or c	Yes
T2a, b, or c	Yes
T3 or 4	No

## How are participants assigned to a procedure in the study?

The WATER IV PCa study is a randomized controlled trial. Participants who enter the study will be randomly assigned Aquablation therapy or radical prostatectomy. The randomization in the study is structured 3 to 1 for Aquablation therapy to radical prostatectomy.

### Study Participants



## What can a participant expect from the study?

- 1. Assessment** – After a study-specific consent form is signed, the physician will review the potential study candidate's medical history, including, but not limited to, MRI, PSA, and biopsy results to confirm eligibility.
- 2. Randomization** – Qualified participants will be randomly to Aquablation therapy or radical prostatectomy.
- 3. Treatment** – Participants will arrive at their treatment appointment and follow all hospital instructions.
- 4. Follow-Up** – Participants will return to meet their care team at regular intervals to conduct brief assessments and provide input on recovery.

Can I get Aquablation therapy to treat prostate cancer without participating in this study?  
No.

Although Aquablation therapy is commonly used to treat enlarged prostates due to benign prostatic hyperplasia (BPH), it is not available outside of this study as a prostate cancer treatment.

**Dr.**  
**and the clinical research team at**

**represent one of the participating sites for this investigational study.**  
**Contact**

**or visit [ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT06651632](https://clinicaltrials.gov/study/NCT06651632)**

The AquaBeam<sup>®</sup> Robotic System and HYDROS<sup>™</sup> Robotic System are not indicated for the treatment of prostate cancer globally. Caution: Investigational device. Limited by Federal (or United States) law to investigational use only.

**References:**

1. <https://www.cancer.org/cancer/types/prostate-cancer/about/key-statistics.html> Accessed on 10/14/2024
2. <https://prostatecanceruk.org/> Accessed on 10/14/2024

**IMPORTANT SAFETY INFORMATION**

**Risk and Safety Information**

All surgical treatments have inherent and associated side effects, some of which may lead to serious outcomes and may require intervention. Individual's outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics and/or surgeon behavior. The most common side effects are mild and transient and may include mild pain or difficulty when urinating, discomfort in the pelvis or penis, blood in the urine, inability to empty the bladder or a frequent and/or urgent need to urinate, and bladder or urinary tract infection. Other risks include but are not limited to: anesthesia risk; sexual dysfunction, including ejaculatory or erectile dysfunction; injury to the urethra, such as false passage or stricture, or to the rectum, including rectal incontinence/perforation; bladder or prostate capsule perforation; infection, including the potential transmission of blood borne pathogens; bleeding; incontinence; embolism; electric shock/burn; transurethral resection (TUR) syndrome; bladder neck contracture; and bruising. No claim is made that the AquaBeam Robotic System will cure any medical condition, or entirely eliminate the diseased entity. Repeated treatment or alternative therapies may sometimes be required.

For more information about potential side effects and risks associated with Aquablation therapy, speak with your urologist or surgeon.

**Rx Only**

Aquablation therapy is performed by urologists. Patients should talk to their doctor to determine if Aquablation therapy is right for them. Patients and doctors should review the potential benefits and limitations of treatment together.