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IRB Approved at the
Protocol Level
Feb 23, 2023

VAPOR 2
STUDY

Prospective, Multicenter,
Single-Arm Study to Evaluate
the Safety and Efficacy of the
Vanquish™ Water Vapor Ablation System for Prostate Cancer

This study is sponsored by

francis MEDICAL

Participating in VAPOR 2

AM I ELIGIBLE?

- If you are ≥50 years of age and have been diagnosed with intermediate-risk prostate cancer, your physician will review your eligibility with you to see if you can participate in the VAPOR 2 study
- If you are a candidate, you will be scheduled to complete a series of tests to further confirm your eligibility to participate

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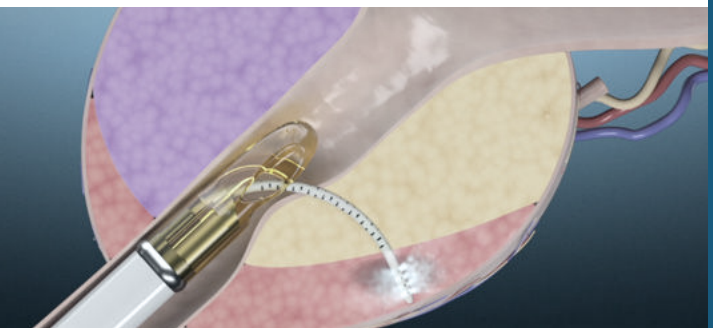
WHAT IS THE VANQUISH™ WATER VAPOR ABLATION SYSTEM?

- The Vanquish Water Vapor Ablation system uses small amounts of water vapor (steam) to ablate (destroy) cancer cells
- The outpatient procedure is performed under general anesthesia
- A device is inserted into your urethra and advanced to your prostate. A small needle shaped catheter is then deployed from the device and moved to the cancerous tissue. The physician will then deliver steam for 10 seconds to destroy the cancer cells.
- Steam may also be delivered to areas around the cancerous tissue to ensure full ablation of the cancer



Understanding VAPOR 2

WHAT TYPE OF STUDY?

The VAPOR 2 study identifies participants who will be treated with the Vanquish™ Water Vapor Ablation system and follows them for 5 years. The study will be conducted at multiple centers in the US.

WHAT IS BEING EVALUATED?

The VAPOR 2 study will evaluate whether the Vanquish system produces a reasonable assurance of safety and effectiveness for the ablation of prostate tissue and for the management of localized intermediate-risk prostate cancer.

WHY SHOULD I PARTICIPATE IN A RESEARCH STUDY?

The National Comprehensive Cancer Network[1] (NCCN) encourages patients to participate in clinical trials and you may benefit as a result of your participation in this study. You will also receive close monitoring of your prostate cancer through the course of the trial. There is, however, no guarantee that you will benefit from your participation in this study, but information learned from the study may help other prostate cancer patients in the future.

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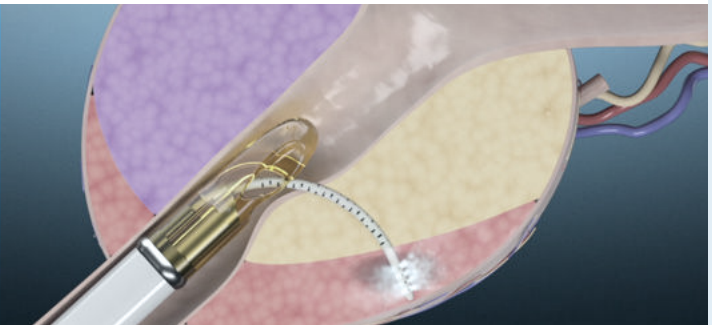

Patient Journey Map

You will be followed for a period of 5 years after initial treatment in the VAPOR 2 clinical study.

1. Screening
Your doctor will review your MRI, lab results and other medical history to see if you are a candidate. If you meet certain criteria, you will be asked to participate and sign a consent.

2. Baseline
Once approved, you will undergo additional tests in preparation for the procedure.

3. Procedure day
The procedure will be done on an outpatient basis. You will be asleep during the procedure and will be discharged with a urinary drainage catheter in place.

4. Catheter removal
Your physician will decide when your urinary drainage catheter can be removed.

Schedule of visits post procedure:

7 day MRI

30 days

90 days

6 months
MRI and biopsy

12 months

18 months

24 months
MRI and biopsy

30 months

36 months
MRI and biopsy

42 months

48 months

54 months

60 months

Your medication usage, PSA, and any symptoms will be assessed at each follow-up visit. You will be given a series of questionnaires intermittently throughout your follow-up. These are given to assess your level of pain or discomfort, urinary function, bowel function, sexual function, and overall quality of life. Additional procedure(s) may be performed if needed.

Common Questions

IS THIS AN EXPERIMENTAL PROCEDURE?
Yes.

WHAT ARE THE RISKS?
As with any procedure and anesthesia there are risks. Your doctor will discuss these risks with you.

HOW WILL I FEEL AFTER THE PROCEDURE?
You may feel some minor discomfort. Your doctor will discuss pain management options with you.

WHEN CAN I RESUME REGULAR ACTIVITIES AND RETURN TO WORK?
Since this is a minimally-invasive outpatient procedure, recovery times are relatively short. Your physician will provide you more detailed information in your discharge instructions.

HOW MUCH WILL IT COST ME?
There are no additional costs to you to be in the study. You will be responsible only for standard of care costs that are normally incurred before, during, and after medical procedures. All study costs incurred outside the normal standard of care are covered by Francis Medical, Inc.

WILL I BE COMPENSATED?
You will not be paid for your participation in this study. You may be compensated for each study visit to assist with expenses associated with travel, meals, parking, etc.

Site PI/RC contact info

Scan the QR code to learn more

1. nccn.org

Creating therapies that are **tough on cancer, gentle on patients**

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