

Why should I participate in this study?

Clinical trials are part of clinical research and at the heart of all medical advances. Clinical trials look at new ways to prevent, detect, or treat disease.

The goal of clinical trials is to determine if a new test or treatment works and is safe.

What is the benefit to me?

If your ablation procedure is a success, you may be able to return to active surveillance and not immediately require a prostatectomy or radiation therapy.

You will receive two PET-CTs with Axumin® and four additional PET-CTs as a part of the long-term follow-up visits. PET-CTs with Axumin® are a newer imaging process that uses a radioactive tracer to help identify prostate cancer cells. This scan may help better detect if prostate cancer has spread beyond the prostate.

The sponsor will compensate up to \$3,500 if you complete all study visits.

How to join the study:

Speak with our study intake team. They can explain the study and help decide if it's a viable option for you.

We'll mail a consent form. You can schedule a video call with our study team and Principal Investigator to discuss the study.

Within driving distance of one of our study sites: We'll schedule a visit at our site for your tolerance test, lab collection and physical exam.

A little further away: We'll do as much as we can remotely and do lab collection along with tolerance test before instillation to reduce your travel.

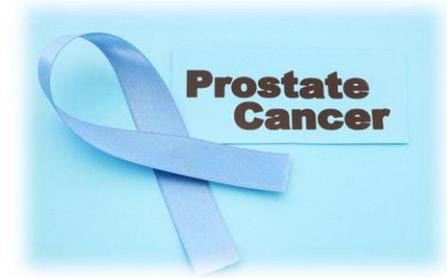
NanoTherm®
Instillation
and Activation

Follow-up at
1 week; 1
month and 4
months with
biopsy

Prostate Cancer Study

A Pivotal, Prospective, Three-Stage, Single-Arm Study of Focal Ablation of the Prostate with NanoTherm® Therapy System for a Limited-Volume, Clinically Localized, Intermediate-Risk Prostate Cancer – Stage 2B

For Patient Use Only



magforce® USA
THE NANOMEDICINE COMPANY



Scan for additional information



NanoTherm® Technology

NanoTherm® Therapy is an investigational approach to the local treatment of solid tumors, like prostate cancer. The method is based on the principle of introducing magnetic nanoparticles directly into a tumor and then heating them in an alternating magnetic field. At approximately 15 nanometers in diameter, the nanoparticles, which are suspended in water, are extremely small (a nanometer is one millionth of a millimeter). The particles are activated by a magnetic field that changes its polarity up to 50,000 times per second, generating heat.



“With the help of prostate cancer patients, we can make a big leap forward in treating this serious condition”

-Ben Lipps, PhD
CEO of MagForce USA

Depending on the duration of treatment and the temperatures achieved within the tumor, the tumor cells are either irreparably damaged or sensitized for additional chemo- or radiotherapy.

With this new procedure, MagForce believes it is possible to combat the tumor from within, while sparing surrounding healthy tissue. Thanks to their coating, the nanoparticles remain at the targeted tumor lesion, allowing for repeated treatments if necessary.

Join our Study

We are looking for patients who have been diagnosed with prostate cancer. If you meet the following criteria, you may qualify to participate.

Study Criteria

IRB Approval:
20162855
#17768266.1

Inclusion Criteria

- Age 40 to 85
- Biopsy confirmed prostate cancer seen on biopsy
- Prostate adenocarcinoma on biopsy
- Biopsy in the last six months showing a lesion that is Gleason 3+4 (Group 2) no larger than 2cc in volume
- PSA <10 ng/ml at the time of screening
- Patient expresses a preference for active surveillance, rather than surgery or radiation, to manage prostate cancer

Exclusion Criteria

- Previous treatment for cancer with radiation, androgen deprivation (including LHRH-agonists or antagonists or antiandrogens), or surgery for prostate cancer
- Active urinary tract infection
- Metallic implants below the neck
- Hematological abnormality indicating increased risk of bleeding or clotting, for example low platelet count or anemia
- Participation concurrently in another clinical trial for prostate disease or in the last 30 days
- Known hypersensitivity to Axumin®

If you would like to participate, contact us at:

MagForce USA, Inc.
Toll Free Phone: (833) 287-1150
Email: prostatestudy@magforce-usa.com
NCT05010759 – www.clinicaltrials.gov
For additional study info visit:
<https://www.magforcestudy.com>