

Background of Study

In 2010 the team of Bernadette Greenwood, BSc, PG Cert., RT (R)(MR) and Roger J. McNichols, PhD conceptualized a unique approach using the Visualase® Thermal Therapy System and the Invivo DynaCAD/DynaTRIM prostate biopsy system to perform Laser Focal Therapy (LFT); aka Laser Interstitial Thermal Therapy (LITT) or Focal Laser Ablation (FLA). This procedure to treat localized prostate cancer was developed at Desert Medical Imaging which began conducting an IRB-approved Clinical Trial in May, 2010. The first case in the world was performed by Dr. John Feller as part of the Phase I, Sponsor Initiated Investigational Study. The outpatient procedure involves placing the patient inside the MRI scanner and displaying MRI images and thermal maps on a computer screen. A thin laser fiber is guided to the tumor and laser energy is applied to heat, coagulate and kill the cancer cells. The temperature and the extent of the ablation zone are constantly monitored with MR imaging. The result is the elimination of MRI-visible cancer with very low risk of side effects. If it is determined through an mpMRI scan and MRI guided biopsy that you might be a good candidate for the procedure, this might be a clinical trial that you may wish to consider.

The Phase I trial demonstrated that Laser Focal Therapy is safe and feasible and further study in a larger patient population Phase II trial is justified. The Phase II trial is underway to study the effectiveness of laser focal therapy to control localized prostate cancer.

Participating in this study is completely voluntary.

IF YOU ARE INTERESTED
IN **JOINING** THIS STUDY,
PLEASE CONTACT THE
RESEARCH TEAM BELOW.

NCT02243033

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INFORMATION FOR PATIENTS

Prostate Cancer
Clinical Trial at DMI



Prostate Cancer
Clinical Trial
for Prostate Ablation in
**Patients with Localized
Prostate Cancer**

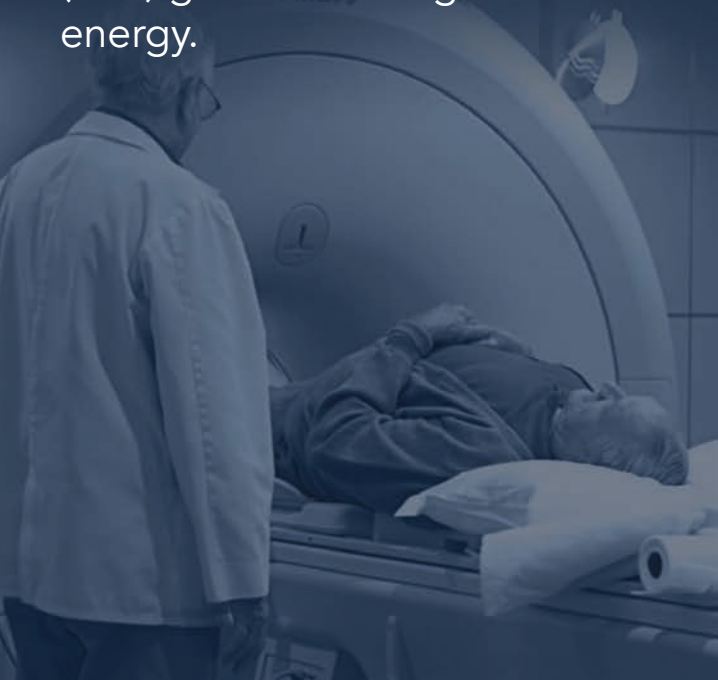


DESERT MEDICAL IMAGING

is Conducting this Study

The purpose of this study is to obtain information on the effectiveness of transrectal delivered MRI guided Laser Focal Therapy.

The system is designed to destroy prostate tissue under Magnetic Resonance Imaging (MRI) guidance using laser energy.



What Is A Clinical Study?

A clinical study is a type of research study. Study staff will explain the clinical trial to you. Clinical trials include only people who choose to take part. If you have any questions, you can ask study staff for more explanation or visit www.clinicaltrials.gov.

What Is The Procedure?

The laser focal therapy procedure (also called LITT or FLA) is designed to destroy prostate tissue under Magnetic Resonance Imaging (MRI) guidance using laser energy. The laser device is FDA 510(k) cleared for clinical use for soft tissue necrotization. The planning system is FDA 510(k) cleared for MRI guided prostate biopsy. DMI is the first site in the world to combine the devices under IRB approved clinical trial NCT 02243033.

Who Can Join This Study?

You can take part in this study of follow up if you are age 45 or older and have been diagnosed with prostate cancer that is low to intermediate risk and is confined to your prostate gland or have recurrent prostate cancer. There are also additional criteria for participating in this study. Study staff will review the full list with you. Approximately 1000 men will participate in this study.

How Often Will I Be Seen?

After the procedure, you will have an ultrasound of your bladder after 48 hours. After that your follow-up visits will be at 6 months and 1 year. PSA testing and surveys will be done at 3 months, 2 years, 3 years and annually for 20 years. This protocol is to track and study rates of biochemical recurrence and metastasis.

Are There Any Risks?

As with many procedures, there are some risks associated with laser focal therapy which can include: pain, bleeding, infection, decrease in seminal fluid volume, incontinence and erectile dysfunction. Study staff will review all the risks associated with the procedure with you and address any questions or concerns.

How Much Will It Cost?

The cost for initial treatment and first year of follow up is \$25,000. Clinical services provided during a clinical trial are either research-related or usual medical care. Research-related services are done to complete the research and the costs are the responsibility of the sponsor of the study. Usual medical care (standard of care) costs include any and all services that are considered medically necessary for your disease and will be billed to your insurance carrier/health plan.