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MRI Guided Transrectal Prostate Laser Ablation for Benign Prostatic Hypertrophy (BPH)

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Protocol Number: Prostate Laser Center BPH 01
Principal Investigator: **Ara Karamanian, MD**
MRI Guided Transrectal Prostate Laser Ablation for BPH

Over 100,000 BPH procedures are performed annually in the US. The purpose of this study is to evaluate the effectiveness of performing MRI guided transrectal laser ablation using a 980 nm laser (Visualase™ by Medtronic, Inc., a Minnesota, U.S.A. company) to treat benign prostatic hypertrophy (BPH). The laser system will be used to necrotize urological soft tissue within the prostate under MRI guidance. This will be a single center, single arm prospective trial with an anticipated enrollment of 10 men. Patients who elect this treatment option and choose to be part of the study will be enrolled consecutively.

https://www.accessdata.fda.gov/cdrh_docs/pdf7/K071328.pdf
"The Visualase Thermal Therapy System is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under magnetic resonance imaging (MRI) guidance in medicine and surgery in cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, orthopedics, pulmonology, radiology, and urology, for wavelengths 800nm through 1064 nm."

Primary outcome measures at baseline, 2 months, 4 months, 6 months and 24 months:

1) Change in International Prostate Symptom Score
2) Change in International Prostate Symptom Score Quality of Life Question
3) Change in BPH Impact Index
4) Change (or lack thereof) in Sexual Health Inventory of Men (SHIM) score
5) Number and severity of adverse events

Inclusion Criteria:

1) Diagnosis of lower urinary track symptoms (LUTS).
2) Prostate volume of 40 – 200 cc.
3) Men ≥ 45 years old.
4) IPSS ≥ 15
5) BPH Impact Index ≥ 5.

Exclusion Criteria:

1) History of prostate or bladder cancer, pelvic radiation, untreated bladder stones, or findings suggestive of likely underlying prostate cancer.
2) Need to catheterize to relieve obstruction.

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3) Daily use of incontinence materials/padding.
4) Neurogenic or hypotonic bladder, Parkinson's Disease, or a history of uncontrolled diabetes.
5) Prior interventional or surgical treatment of BPH.
6) Penile prosthesis.
7) Artificial urinary sphincter or collagen bladder injection.
8) Urethral stricture.
9) Bleeding disorder/coagulopathy.
10) Inability to refrain from blood thinners in the peri-procedural period.
11) Inability or chooses not to provide informed consent.
12) Any serious medical condition which would make proceeding to treatment unsafe.
13) Significant contraindication to MRI or gadolinium contrast.
14) Hip replacement.
15) Lack of a rectum.
16) Life expectancy of less than two years.
17) Unable or unwilling to complete all required questionnaires and follow-up assessments.

Data Collection:

Patients will complete the follow-up surveys at home and mail, fax, or scan and e-mail them in. They will fill up survey forms related to their SHIM, IPSS with QOL, and BPH Impact Index (as described in the outcome measures).

Statistical Analysis:

We will perform a repeat analysis of variance (rANOVA) on each patient's survey results for all timepoints. Pairwise p-values between pre-ablation and subsequent timepoints will be calculated.

Risk / Safety Information:

Patients will also be consented with the general treatment, specific procedure and sedation consent forms, included. Risks are described in those documents.

Unanticipated problems will be reported to the IRB office.

I am establishing a physician-patient relationship with those participating in the study. I will management medical complications should they arise and involve physicians of other specialties as needed.

Monitoring and reporting of Adverse Events:

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The Investigator will be responsible for overseeing the project and will monitoring all adverse events. Any event deemed to be an "unanticipated problem" as defined by the IRB will be reported to the IRB as required. The principal investigator and his staff will be in regular communication with patients and patients will be instructed to self report adverse events.

Informed consent:
Each participant will have ample time to review the informed consent and ask questions prior to signing the document. Each participant will receive a copy of the signed informed consent.

Confidentiality:
The data will be compiled into an encrypted excel spreadsheet that is only accessible on encrypted computers requiring secure log-in and via online access (Office 365) requiring secure log-in. Only the principle investigator and staff that has been HIPAA trained and signed the study confidentiality form will have access to the data.

Intended Use of Data:
The intention is to publish the data in a peer reviewed journal and on ClinicalTrials.gov. The data will be de-identified and compiled prior to publication. MRI images without any identifiers will also be published.