Cover Page

Study Title:

Prostatic Artery Embolization (PAE) for Treatment of Signs and Symptoms of Benign Prostatic Hyperplasia (BPH)

NCT:

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Prostatic Artery Embolization (PAE) for Treatment of Signs and Symptoms of Benign Prostatic Hyperplasia (BPH)

Title	**Prostatic Artery Embolization (PAE) for Treatment of Signs and symptoms of Benign Prostatic Hyperplasia (BPH)**
Short Title	PAE for BPH
Protocol Number	V 12.3.19
Phase	Pilot study
Methodology	Open labeled, non-randomized feasibility study
Study Duration	We estimate it will take approximately 2 years to fully enroll and complete the study.
Study Center(s)	Single Center, Northwestern: (Northwestern University, Northwestern Memorial Hospital and Northwestern Memorial Faculty Foundation)
Objectives	Primary Objective: Evaluate the safety of PAE for the treatment of lower urinary tract symptoms (LUTS) attributed to BPH.
Number of Subjects	30
Diagnosis and Main Inclusion Criteria	Subjects with LUTS secondary to BPH refractory to/contraindicated for medical treatment
Study Product(s)	BeadBlock® Embolic Beads, BTG International, given intra-procedurally
Duration of administration	Dose given one-time during interventional radiology PAE procedure, given by and at the discretion of the interventional radiologist PI or SubI's
Statistical Methodology	Descriptive Statistics will be employed.

STUDY OBJECTIVES

Primary Objectives

Endpoint #1: Patient safety

The Primary Objective of this pilot study is to evaluate the safety of PAE for the treatment of LUTS attributed to BPH. Primary Safety Endpoints include:

1. A reduced incidence and severity of adverse events compared with historical TURP morbidity rates. These include genitourinary events (i.e., events associated with the urinary tract and/or the surrounding genital region)

2. Damage to the bladder floor, trigone, sphincters, and rectum

3. Incontinence as defined by International Continence Society (ICS) male IS score of at least +6 from baseline.

4. Infections

5. Secondary surgical interventions

6. All transient post-procedure events (i.e. *catheter dwelling time)*

7. Deaths

Endpoint #2: Objective clinical endpoints (measured at baseline, 4 weeks, 12 weeks, 6 and 12 months)

1. Change in International Prostate Symptom Score (IPSS)

2. Change in QoL bother question

3. Change in BPH impact index

4. Change in Qmax (*peak and total void volume at each followup visit)*

5. Change in Post Void Residual (PVR) Volumes: Measure PVR at each follow-up visit to monitor impairment or improvement of bladder emptying due to the treatment or disease progression

6. Change in Detrusor Muscle Pressure (Pdet) at Peak Urine Flow (Qmax)

7. Change in International Index of Erectile Function (IIEF- EF) domain

8. Change in Male Sexual Health Questionnaire (MSHQ)

9. Change in Prostate Volume

10. Cystoscopic appearance of the prostatic urethra

Endpoints:

Preliminary Safety (Primary Endpoints) will be assessed during treatment and at post-treatment intervals of 1, 3, 6 and 12 months. Preliminary effectiveness (Secondary Endpoint) will be evaluated based on International Prostate System Score (IPSS) and cystoscopic visualization of the subject's urethra, prostate and bladder based on the timeline listed in the protocol.

Study Design

This pilot study will be a single center, open labeled, non-randomized feasibility study to evaluate the initial safety of the PAE for the treatment of symptomatic BOO. 30 adult male subjects will be enrolled in this study.

Statistical Analysis

General considerations: continuous variables will be summarized as n, mean, standard deviation, median, minimum and maximum. Categorical variables will be summarized as the number and percentage of patients in each category.

This is a single center pilot proof of concept study aiming to evaluate the safety, efficacy, and tolerability of PAE for the treatment of signs and symptoms BPH. A small number of subjects will be recruited for this purpose (30 subjects). We estimate it will take approximately 3 years to recruit, treat, and

complete follow up on 30 subjects.

No large randomized studies using PAE to treat BPH have been done to date. The sample size has

been chosen to evaluate PAE using a US population. The results of the study will provide critical preliminary data to later guide in powering a more statistically robust, and larger randomized controlled trial in the future.

Sample size justification

To detect a statistically significant reduction from baseline in IPSS at 12 weeks, a sample size of 30 patients is computed based on the following assumptions:

- 85% power
- 2-sided alpha of 0.05
- Mean reduction of 5 points
- SD of reduction of 8 points The sample size of 28 is rounded up to 30 patients to take account of approximately 15% of patients who drop-out of the study.

Planned analysis of clinical endpoints

Change in IPSS, QoL bother question, BPH impact index and Qmax will be assessed using a one- sample t-test. A log transformation may be applied if required to adjust for skewed data. In addition a non-parametric Wilcoxon test will also be performed.