The Study Design

Title

The safety and efficacy of irreversible electroporation versus standard medication for the treatment of benign prostatic obstruction: a randomized controlled trial

Aims

Aim: To investigate the safety and feasibility of irreversible electroporation for patients with benign prostatic obstruction.

Inclusion Criteria

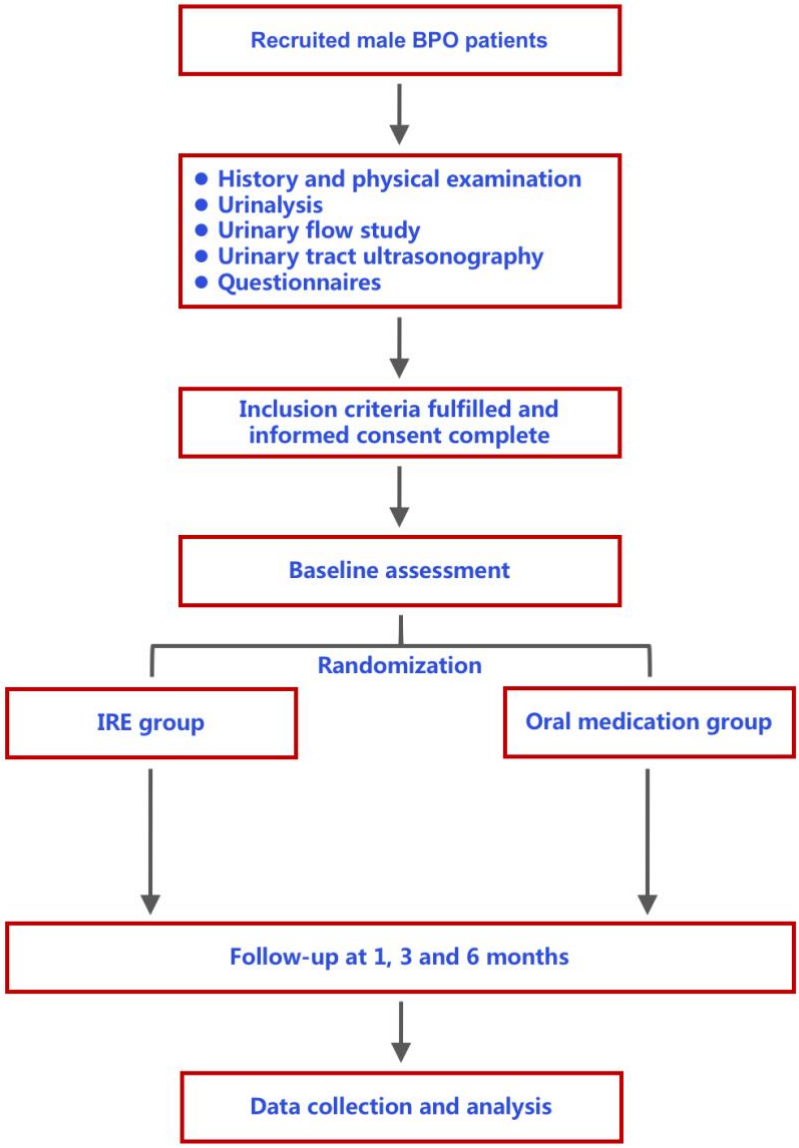
1. Male, 45 years or older.
2. The presence of voiding symptoms, i.e. slow stream, intermittent stream, hesitancy, straining, etc.
3. Q_{max} ≥ 5 mL/s and ≤ 15 mL/s with minimum voided volume of 125 mL or more during flow study.
4. The presence of bladder outlet obstruction during pressure-flow study.
5. International Prostatic Symptom Score (IPSS) ≥ 12 at screening.
6. Prostate volume ≥ 30 ml (using a transrectal ultrasound approach).
7. Total serum prostatic specific antigen (PSA) ≥ 1.5 ng/mL and ≤ 10 ng/mL at screening.
8. Subject is able to communicate and complete the questionnaires properly.
9. Written informed consent.

Exclusion Criteria

1. Diagnosis or suspicion of bladder, prostate, urethral or pelvic tumor.
2. Patients with arrhythmia or history of cardiac pacemaker implantation.
3. Known lower urinary tract or pelvic surgical history.
4. Voiding symptoms as a result of urethral stricture, stone diseases, chronic prostatitis, space-occupying lesions etc.
5. Known neurogenic or congenital lower urinary tract dysfunction.

6. Rigid or flexible cystoscopy examination within the past 7 days at screening.
7. Existence of anatomical abnormalities of the urinary tract (e.g. diverticulum of the bladder or urethra, ectopic ureteral orifice etc.).
8. The presence of acute conditions, such as, urinary tract infection, fever, heart failure etc.
9. Patients with poor compliance or cognitive competence.

Study design flow diagram



Primary Outcomes

1. The changes of maximum flow rate (ml/s) between baseline and during follow-up: Maximum flow rate will be measured using urinary flow study. Measured at baseline and 1, 3, 6 months during follow-up.

Secondary Outcomes

1. The changes of IPSS scores between baseline and during follow-up: Measured using a standard IPSS scoring system. Measured at baseline and 1, 3, 6 months during follow-up.
2. The changes of IIEF scores between baseline and during follow-up: Measured using a standard IIEF scoring system. Measured at baseline and 1, 3, 6 months during follow-up.
3. The changes of maximum detrusor pressure at maximum flow rate between baseline and during follow-up: The data will be captured during pressure flow study. Measured at baseline and 3, 6 months during follow-up.
4. The changes of post void residual volume (ml) between baseline and follow-up: post void residual volume (ml) will be measured via ultrasound. Measured at baseline and 1, 3, 6 months during follow-up.
5. The changes of prostate volume (ml) between baseline and follow-up: Prostate volume (ml) will be measured using transrectal prostate ultrasound and calculated as: prostate volume (ml) = length (mm) * width (mm) * height (mm) * 0.52. Measured at baseline and 1, 3, 6 during follow-up.
6. The documentation of IRE procedure and medication related side effects. Measured at baseline and 1, 3, 6 months during follow-up.

Brief Summary

Irreversible electroporation (IRE) is a novel ablation modality using electric pulses to create nanoscale defects in the cell membrane. It has been verified to be safe on the treatment of prostate, lung, liver and kidney masses. The present is a randomized, controlled trial, with a main purpose of looking into the safety and feasibility of irreversible electroporation for patients with benign prostatic obstruction.

Detailed Description

Benign prostatic obstruction (BPO) is the main reason to cause lower urinary tract symptoms (LUTS) in aged male. Oral medications, such as, α 1-adrenoceptor antagonist and 5 α -reductase inhibitors are the mainstay treatment options. However, some patients can not tolerate long-term use, due to either side effects or limited efficacy. Though transurethral resection or enucleation of prostate usually achieve significant symptom improvement, it's an end stage procedure and it is only reserved for carefully selected patients.

The development of focal ablative therapy yields minimally invasive treatment option for primary tumors such as the liver, lung, pancreas, kidney, and prostate. Among the novel techniques are cryoablation, radiofrequency ablation (RFA), microwave ablation, and high-intensity focused ultrasonography. Irreversible electroporation (IRE) is a one of the ablation modalities using electric pulses to create nanoscale defects in the cell membrane. IRE is not dependent on thermal energy and is therefore causing minimum damage to the blood vessels, nerves and tissue architecture. The present is a randomized, controlled trial, with a main purpose of looking into the safety and feasibility of irreversible electroporation for patients with benign prostatic obstruction.

Key Words

male, lower urinary tract symptoms, benign prostatic obstruction, irreversible electroporation, urodynamics

Description of Two Groups

IRE group

Oral medication group