Safety and Feasibility of a Transurethral Endoscopic Procedure for the Luminal Restoration of the Prostatic Urethra: A Preliminary Investigation

ACTRN12609000760279

Status RECRUITING
Sponsor NeoTract, Inc.
Enrollment 70 participants

Plain Language Summary

This study is testing a new minimally invasive procedure for men with an enlarged prostate (benign prostatic hyperplasia, or BPH) that is causing urinary problems. The procedure uses a device called the NeoTract Anchor System, which is inserted through the urethra (the tube that carries urine from the bladder) and holds back the enlarged prostate lobes to widen the urinary passage. This is different from traditional prostate surgery because no tissue is removed or burned. The study will track whether this approach safely improves urinary flow and reduces symptoms over 7 years.

You may be eligible if:
- You are a male aged 55 years or older
- You have been diagnosed with BPH causing lateral lobe obstruction
- Your urinary symptom score (IPSS) is greater than 13
- Your urine flow rate is between 5 and 12 mL/sec
- Your prostate is between 20 and 100 grams in size
- Your PSA has been stable over 2 years

You may NOT be eligible if:
- You have had previous prostate surgery or non-medication prostate treatments
- You have a history of urinary retention
- Your post-void residual urine is above 250 mL
- You have a PSA above 10 ng/mL
- You have bladder, prostate, or urethral conditions that affect voiding
- You are on anticoagulant medications (other than aspirin or clopidogrel)
- You are interested in future fertility

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (16)

- Diagnosis of lateral lobe symptomatic BPH
- IPSS Symptom score >13
- Peak urine flow rate> than 5ml/sec but
- <12ml/sec on a voided volume > 125 ml
- Prostate volume >20 grams to <100

... and 11 more (see full listing online)

Exclusion (74)

- Mental capacity, dementia or inability to

• give informed consent.
• Subject in retention, or with a previous
• history of urinary retention.
• Post void residual volume >250 ml by
... and 69 more (see full listing online)

Locations (1 total)

Australia