Urodynamic effect of Prostate Artery Embolization for lower urinary tract symptoms due to benign prostate hyperplasia

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Primary Objective: - To determine the urodynamic effects of PAE on bladder outlet resistance (BOR), Qmax, bladder contractility, and post-void residual (PVR).Secondary Objective(s): - IPSS/QoL scores.- Prostate Volume.- Prostate Specific Antigen...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON40877

Source
ToetsingOnline

Brief title
UroPE study

Condition

- Urinary tract signs and symptoms
- Prostatic disorders (excl infections and inflammations)

Synonym
prostate hyperplasia; lower urinary tract symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Embolization, Prostate Artery, Prostate hyperplasia, Urodynamic effect

Outcome measures

Primary outcome

The primary outcome measure is the urodynamic reduction of bladder outlet obstruction. Cystometry and urodynamic pressure flow are studied by assessing the following bladder outlet resistance parameters: Schäfer grade, BOOI (Bladder Outflow Obstruction Index = Abrams-Griffiths number), and urethral resistance factor (URA; >29 cm H2O =obstructed).

Secondary outcome

Post treatment IPSS, IPSS/QOL, PV, PSA are presented as means and standard deviations or medians (interquartile ranges) and are compared to baseline. Wilcoxon signed-rank tests or a paired t-test are used for statistical analysis.

Study description

Background summary

TURP is the golden standard for the surgical treatment of LUTS refractory to conservative therapy. PAE is a new promising minimal invasive treatment option. Urodynamic effects of PAE have not yet been investigated.

Study objective

Primary Objective:

- To determine the urodynamic effects of PAE on bladder outlet resistance (BOR), Qmax, bladder contractility, and post-void residual (PVR).

Secondary Objective(s):
- IPSS/QoL scores.
- Prostate Volume.
- Prostate Specific Antigen level.
- Duration of hospitalization post procedure
- Duration of post procedure catheterization
- To evaluate overall and procedure related adverse events.

Study design

A prospective non-randomized single-centre study to investigate urodynamic efficacy

Intervention

30 patients with debilitating LUTS due to BPH, refractory to pharmacotherapy are selected to undergo angiographic embolization of the prostatic arteries with microspheres.

Study burden and risks

Previous studies on PAE show no major complications and considerable rates of clinical improvement (9-13).
Risk involved with the individual study procedures are related to contrast nephropathy and allergy (CT and DSA), femoral access complications and non-target embolization.
Based on the safety profile from the literature, we consider the potential benefit to outweigh the small risks on complications.

In case of no clinical improvement after PAE, patients are still eligible to undergo the usual therapy (TURP).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Male patients, > 40 years
- Lower urinary tract symptoms (LUTS) secondary to Benign Prostate Hyperplasia (BPH)
- Symptoms refractory tomedical therapy(*-adrenergic antagonist and 5*-reductase inhibitor for at least 6 months), or contraindication to medical therapy.
- Patient must be eligible candidate for Transurethral Resection of the Prostate (TURP)
- IPSS (International Prostate Symptom Score) >18 and QoL >3, or both
- BOR (Bladder Outlet Resistance) Schäfer grade *2
- PV (Prostate Volume) > 30 cm^3.
- PVR (Post-Void Residual) * 100 ml.
- Qmax (maximum flow rate) * 15 ml/sec.
- Patient has given written Informed consent

Exclusion criteria

1. Active urinary tract infection or prostatitis
2. Suspicion of prostatic carcinoma during urologic work up for LUTS due to BPH.
3. Bladder atonia, acute urinary retention, neurogenic bladder disorder or other neurological disorder that is impacting bladder function (eg multiple sclerosis, Parkinson's disease, spinal cord injuries, etc),
4. Urethral stricture, bladder neck contracture, sphincter abnormalities, urinary obstruction due to causes other than BPH, or other potentially confounding bladder or urethral disease or

condition
5. Cystolithiasis or chronic hematuria within 3 months prior to study treatment
6. History of pelvic irradiation or radical pelvic surgery
7. Use of medication with negative effect on detrusor function.
8. Previous surgical procedures, TURP, needle ablation, microwave or laser therapy, balloon dilation, stent implantation, or any other invasive treatment to the prostate or urethra.
9. Unable to undergo Magnetic Resonance Imaging
10. Allergy to iodinated contrast agents
11. Known upper tract renal disease or GFR * 59
12. Contraindications for angiography according to the UMC Utrecht standard of practice.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-06-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL47710.041.14