Embolisation of the prostatic artery in patients with symptomatic benign prostate hyperplasia: A prospective single arm cohort-study.

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The assess the safety and efficacy of prostate artery embolization (PAE) with polyethylene glycol microspheres (PEGM) in patients with low urinary tract symptoms (LUTS) due to benign prostate hyperplasia (BPH).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms male benign
Study type	Interventional

Summary

ID

NL-OMON52683

Source
ToetsingOnline

Brief title
EMBO-PROST

Condition

- Reproductive neoplasms male benign

Synonym
benign prostate hypertrofia, benign prostate tumour

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis

Source(s) of monetary or material Support: Terumo Europe

Intervention

Keyword: BPH, PAE, prostate

Outcome measures

Primary outcome

To assess the effect (Δ IPSS) after 3 months of prostate artery embolization (PAE) with polyethylene glycol microspheres (PEGM) in patients with low urinary tract symptoms (LUTS) due to benign prostate hyperplasia (BPH).

Secondary outcome

Secondary parameters

- Assessment safety defined as adverse events:

o expected side-effects:

* e.g. pelvic pain, worsening of direct obstructive and irritative symptoms, extension of inflammatory effect to adjacent symptoms, transient increase urinary frequency, burning urethral pain.

o unexpected complications:

* e.g. vascular complication, non-targeted embolization, erectile dysfunction, incontinence, retrograde ejaculation, urinary tract infection, bladder necrosis, (acute) urinary retention, hematuria, rectorrhagia, hematospermia, radiodermatitis, skincancer.

- Assessment during 12 months follow up; Δ IPSS, Δ prostate volume (PV), Δ prostate specific antigen (PSA), Δ post void residual urine volume (PVR), Δ Qmax, Δ IPSS, Δ erectile function score (IIEF) and Δ quality of life (Qualeffo).

- PAE costs

- Assessment of predictors of good clinical outcome e.g. Zonal Volumetry index, number of nodules >= 2, percentage necrosis on MRI and Δ

Exploratory parameters

The off-line evaluation of the clinical performance of Philips EmboGuide in PAE procedures (EmboGuide will not be used during all procedures)

a. Parameters related to the use of XperCT and EmboGuide:

i. Procedure time (defined as time between first exposure run and last exposure run)

ii. Successful detection of prostatic artery (First time right, Manual correction needed, Failed to detect)

iii. Accumulative procedure dose (Total DAP in Gy.cm2)

Study description

Background summary

Benign prostate hyperplasia (BPH) is one of the most common pathologic entities in men, affecting over 50% of men older than 60 years of age, and over 90% of men older than 80 years (1-4) . Although this condition is benign, BPH may cause low urinary tract symptoms (LUTS). To objectively quantify LUTS in patients the International Prostate Symptom Score (IPSS) is used. BPH with LUTS is generally treated conservatively with medical therapy. Although many patients will demonstrate improvement, a substantial proportion will not benefit from conservative therapy. Patients with symptoms refractory to medical therapy are potential candidates for minimally invasive or surgical procedures. The golden standard therapy is trans-urethral resection of the prostate (TURP), with high success- and low morbidity-rates. However, in high volume BPH cases the TURP success-rate drops, re-interventions are more often needed and a

higher (post-)procedural morbidity-rate is reported.(5). Therefore open-prostatectomy, a more invasive treatment, in large volume BPH is needed. Although open-prostatectomy demonstrates good clinical results it can be related to serious major complications which can be a threat for the elderly patient.
Prostate artery embolization (PAE) is a minimal therapy for patients with BPH and LUTS with promising results. (6,7) As opposed to the former, the efficacy-rates for PAE in high volume BPH are promising with only few reported adverse events; side-effects and complications. (8,9) PAE is a valuable treatment alternative to transurethral surgery in patients with symptomatic BPH.

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5. Reich O, Gratzke C, Bachmann A, et al. Morbidity, mortality and early outcome of transurethral resection of the prostate: A prospective multicenter evaluation of 10,654 patients. J Urol. 2008;180(1):246-249.
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9. Wang XY, Zong HT, Zhang Y. Efficacy and safety of prostate artery embolization on lower urinary tract symptoms related to benign prostatic hyperplasia: A systematic review and meta-analysis. Clin Interv Aging. 2016;11:1609-1622.

Study objective

The assess the safety and efficacy of prostate artery embolization (PAE) with polyethylene glycol microspheres (PEGM) in patients with low urinary tract symptoms (LUTS) due to benign prostate hyperplasia (BPH).

Study design

Prospective single-arm cohort study.

Intervention

After out-patient urology consultation and informed consent, patients undergo in-patient PAE. Before PAE all patients have blood examination (GFR, CBC, creat, PSA, coagulation status) and corrected accordingly. Bilateral puncture of the common femoral artery is performed, placing a 4F catheter in the contralateral internal iliac artery for diagnostic imaging (DSA) in cranio-/oblique (10°/40°) projection (± 3D angiography and/or coned beam CT) in order to identify the main branches and the origin of the prostatic artery on each side. A micro catheter is selectively placed distally in the prostatic artery. In case of collateral pathways to non-targeted areas, a proximal coiling of these branches will be performed. Embolization using polyethylene glycol microspheres (PEGM), sized 400µm and/or 600 µm (HydroPearl®). The embolization end point is until stasis of the contrast is achieved.

Study burden and risks

vascular complication, e.g. inguinal hematoma (1.9%),
non-targeted embolization, e.g. bladder necrosis, <0.1%
erectile dysfunction, (?%)
incontinence, (?%)
retrograde ejaculation, (?%)
urinary tract infection, (2.9%)
(acute) urinary retention, (9.5%)
hematuria, (6.8%)
rectorrhagia, (4.5%)
hematospermia, (5.8%)
stochastic en deterministic effects due to exposure of per-procedural X-ray.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

men > 40 years with urinary tract symptoms due to BPH, refractory to medical therapy
prostate size > 50cc measured by trans-rectal US and/or CT and MRI
IPSS score>18
Qol >2
Qmax <12

Exclusion criteria

Prostate/bladder malignancy
neurogenic bladder
detrusor failure
hyper-/hypoactive bladder
urethral strictures
dysfunction/contraction bladder neck
bladder calculi of diverticula
renal insufficiency (GFR <60ml/min)
prostatitis
interstitial cystitis
severe atherosclerosis with tortuosity of afferent arteries and/or allergy to intravenous contrast
Patient not allowed in MRI

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-08-2019
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	HydroPearl® - Compressible microspheres for embolisation
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-02-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	20-11-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	10-06-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	

Date:	21-03-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20499
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL63097.028.18
OMON	NL-OMON20499