Prostate embolization for patients with symptomatic benign prostate hyperplasia: a prospective, single arm cohort study.

Published: 21-10-2019
Last updated: 13-01-2025

PAE results in significant IPSS reduction

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20499

Source
NTR

Brief title
EMBO PROST

Health condition

benign prostate hyperplasia, BPH.

Sponsors and support

Primary sponsor: Terumo
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Objectify reduction IPSS 3 months after PAE, with PEGM, in patients with LUTS due to BPH.

Secondary outcome

Objectify safety, defined as side effect; Expected side effects: 1. pelvic pain 2. progressive complaints of direct obstructive/irritrative symptoms 3. extension of inflammatory effect to adjecents symptoms 4. transient increased urinary frequency 5. burning urethral pain. Unexpected side effects: 1. Vascular complications 2. non-targeted embolisation 3. erectile dysfunction 4. incontinence 5. Retrograde ejaculation 6. urinarytract infection 7. bladder necrosis 8. (acute) urinary retention 9. hematuria 10. rectarrhagia 11. hematospermia 12. radiodermatitis 13. skincancer.

Study description

Background summary

Prostate embolization for patients with symptomatic benign prostate hyperplasia: a prospective, single arm cohort study.

Study objective

PAE results in significant IPSS reduction

Study design

* 2 week before inclusion (out-patient clinic) * Inclusion (out-patient clinic) * PAE in hospital * + 1wk post-procedural (consult by phone) * + 3mnd post-procedural (out-patient clinic) * + 6mnd post-procedural (out-patient clinic) * + 12mnd post-procedural (out-patient clinic)

Intervention

PAE, prostate artery

Contacts

Public
ETZ
Sven Adriaansens

0031132210379
Scientific

ETZ
Sven Adriaansens

0031132210379

Eligibility criteria

Inclusion criteria

men > 40 years, with LUTS due to BPH, refrectory to medical therapy, Size > 50cc, IPSS > 18, Qol>2, Qmax<12.

Exclusion criteria

malignancy prostate or bladder, neurogenic bladder, diverticula/calculi, urethra strictures, dysfunction bladderneck, eGRF < 30, prostatits, cystitis, atherosclerosis AII, allergy to i.v. contrast

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: No

Plan description
x

Ethics review

Positive opinion
Date: 21-10-2019
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52683
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8129
CCMO	NL63097.028.18
OMON	NL-OMON52683

Study results

Summary results
x