Clinical and histologic effect of transrectal intraprostatic injections with botulinum toxin A in patients with lower urinary tract symptoms caused by benign prostatic hyperplasia.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20354

Source
Nationaal Trial Register

Brief title
BOP1

Health condition

Benign prostatic hyperplasia

Sponsors and support

Primary sponsor: University Medical Center Utrecht, Utrecht
The Netherlands
Source(s) of monetary or material Support: Allergan

Intervention

Outcome measures

Primary outcome

Symptom relief according to the International Prostatic Symptom Score(IPSS)

Secondary outcome

1. Urodynamic obstruction (according to Schafer)

2. Post void residual

3. Decrease in prostate volume

4. Histologic change after 1 month

5. PSA change

6. Other treatment needed

Study description

Background summary

Rationale:
The standard treatment of lower urinary tract symptoms due to benign prostatic hyperplasia, not responding to medication, is transurethral prostatic resection. This is an invasive procedure requiring general or regional anestesia. Intraprostatic injection of Botox causes relaxation of smooth muscle tissue and causes cellular apoptosis. Therefore it is possibly effective for treatment of benign prostatic hyperplasia. Transrectal prostatic injection is minimally invasive and can be performed without anestesia in the outpatient clinic.

Objective:
To determine the subjective effect on lower urinary tract symptoms and to determine objective urodynamic and histologic changes after intraprostatic botulinum toxin injection.

Study design:
Prospective.

Study population:
Male patients with lower urinary tract symptoms due to benign prostatic hyperplasia, not responding to medication.

Intervention:

Transrectal injection of botulinum toxin into the prostate.

Main study parameters/endpoints:
Symptom relief (IPSS).

Urodynamic obstruction (according to Schafer)

Post void residual

Decrease of prostate volume

Histologic changes after 1 month.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
At least 8 visits to the outpatient clinic are necessary. Four urodynamic studies will be performed (in total 4 hours). Patients will be asked to fill out questionnaires and voiding diaries with every visit.
There is a risk for prostatitis and a risk for hemorrage due to the prostatic biopsy and after the intraprostatic injection. Furthermore there is a risk for side effects of the botulinum toxin like allergy (infrequently), aritmia and respiratory problems in case of overdose.

Study objective

Botulinum toxin type A injection of the prostate causes relaxation and cellular apoptosis and by this way will relieve lower urinary tract symptoms in patients with benign prostatic hyperplasia.

Intervention

Transrectal intraprostatic injection with botulinum toxin type A

Contacts

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Eligibility criteria

Inclusion criteria

1. Age > 55

2. Signed informed consent

3. LUTS with IPSS (international prostatic symptom score)
> 7

4. Insufficient respons to oral medication

5. Prostatic volume 30-50 ml

6. Urodynamic infravesical obstruction > grade II according to Schafer

7. Willing and able to fill out questionnaires and voiding diaries

8. Willing and able to attend proposed investigations

Exclusion criteria

1. Neuropathic bladder dysfunction

2. Prostatic carcinoma

3. Coagulation disorder

4. Urinary tract infection

5. Bladder calculus

6. Postrenal renal insufficiency

7. Myopathic disorder

8. Anatomical defects preventing transrectal approach

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL739
NTR-old	NTR749
Other	: N/A
ISRCTN	ISRCTN42633050

Study results

Summary results
N/A