

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

Submission date
22/11/2006

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
22/11/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
06/01/2021

Condition category
Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

NL739, NTR749

Study information

Scientific Title

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

Acronym

BOP1

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Prospective clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Benign prostatic hyperplasia

Interventions

Transrectal intraprostatic injection with botulinum toxin type A.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Botulinum toxin type A

Primary outcome(s)

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

Key secondary outcome(s)

1. Urodynamic obstruction (according to Schafer)
2. Post-void residual
3. Decrease in prostate volume

4. Histologic change after one month
5. Prostate Specific Antigen change
6. Other treatment needed

Completion date

31/03/2008

Eligibility

Key inclusion criteria

1. Age more than 55
2. Signed informed consent
3. Lower Urinary Tract Symptoms (LUTS) with International Prostatic Symptom Score (IPSS) more than seven
4. Insufficient response to oral medication
5. Prostatic volume 30 to 50 ml
6. Urodynamic infravesical obstruction more than grade II according to Schafer
7. Willing and able to fill out questionnaires and voiding diaries
8. Willing and able to attend proposed investigations

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Total final enrolment

15

Key exclusion criteria

1. Neuropathic bladder dysfunction
2. Prostatic carcinoma
3. Coagulation disorder
4. Urinary tract infection
5. Bladder calculus
6. Post-renal renal insufficiency
7. Myopathic disorder
8. Anatomical defects preventing transrectal approach

Date of first enrolment

01/10/2006

Date of final enrolment

31/03/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Utrecht

Utrecht

Netherlands

3508 GA

Sponsor information

Organisation

University Medical Center Utrecht (UMCU) (The Netherlands)

ROR

<https://ror.org/0575yy874>

Funder(s)

Funder type

Industry

Funder Name

Allergan (International)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2012	06/01/2021	Yes	No