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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

Registration date
22/11/2006

Overall study status
Completed

Last Edited
06/01/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Prospective clinical trial

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/10/2006

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

Age group
Adult

Sex
Not Specified

Target number of participants
20

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)

Sponsor details
P.O. Box 85500
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3508 GA

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Industry

Funder Name
Allergan (International)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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