

# 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

☒ Results

☐ 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

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

Utrecht

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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?
<a href="#">Results article</a>	results	01/10/2012	06/01/2021	Yes	No