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

Gepubliceerd: 07-08-2006 Laatst bijgewerkt: 13-12-2022

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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20354

Bron
Nationaal Trial Register

Verkorte titel
BOP1

Aandoening

Benign prostatic hyperplasia

Ondersteuning

Primaire sponsor: University Medical Center Utrecht, Utrecht
The Netherlands
Overige ondersteuning: Allergan

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

Transrectal intraprostatic injection with botulinum toxin type A

Contactpersonen

Publiek

University Medical Center Utrecht (UMCU),
P.O. Box 85500
L.M.O. Kort, de
Utrecht 3508 GA
The Netherlands
+31 (0)30 2508079

Wetenschappelijk

University Medical Center Utrecht (UMCU),
P.O. Box 85500
L.M.O. Kort, de
Utrecht 3508 GA
The Netherlands
+31 (0)30 2508079

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2007
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL739
NTR-old	NTR749
Ander register	: N/A
ISRCTN	ISRCTN42633050

Resultaten

Samenvatting resultaten
N/A