The effect of Botulinum toxin A injections for overactive bladder on detrusor contractility

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The objective is to find out whether injection of Botulinum toxin A into the wall of the bladder has, besides effects on bladder capacity and urgency symptoms, any influence on the contractility of the detrusor muscle.

Ethical review	Approved WMO
Status	Pending
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON31265

Source
ToetsingOnline

Brief title
Botulinum toxin A and detrusor contractility

Condition

- Urinary tract signs and symptoms

Synonym
overactive bladder, urine incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: botulinum toxin, contractility, detrusor, overactive bladder

Outcome measures

Primary outcome

The main endpoint is the change in detrusor contractility after Botulinum toxin

A treatment.

Secondary outcome

The secondary endpoint is the change in post void residual volume in relation

to the detrusor contractility.

Study description

Background summary

Botulinum toxin A (BT-A) causes muscle relaxation when injected intramuscular. The protein works peripherally and does not cross the blood-brain barrier. In patients with overactive bladder (OAB) injection with Botulinum toxin A into the bladder wall has shown to reduce complaints of urgency, frequency and urge-incontinence. The working mechanism of BT-A in the peripheral tissue, the muscle itself, is known to some extent. BT-A is believed to act on both the afferent and the efferent branch of the micturition regulation circuitry. The effect of the BT-A treatment on the contractility of the detrusor has never been investigated. This is remarkable, since this factor could provide information about both the wordking mechanism of BT-A and the predisposing factors for the need for intermittent catheterisation after the treatment.

Study objective

The objective is to find out whether injection of Botulinum toxin A into the wall of the bladder has, besides effects on bladder capacity and urgency symptoms, any influence on the contractility of the detrusor muscle.

Study design

This is a prospective pilot study in which patients with OAB will fill out a micturition diary and Quality of Life-questionnaire and undergo an urodynamic

investigation before and six weeks after their treatment with BT-A injections.

Intervention

Before the treatment patients undergo urodynamic measurements to establish the baseline value of detrusor contractility. Then the Botulinum toxin A is injected into the detrusor muscle during an endoscopic procedure. Six weeks after the injection, a second urodynamic investigation is carried out to establish any changes in the detrusor contractility. Also patients will fill out a micturition diary Quality of Life-questionnaire before and after the treatment, to objectify the effect of the treatment on the patients symptoms.

Study burden and risks

The study is performed in patients who are already planned for the procedure of Botulinum toxin A injections. Urodynamics before injection of BT-A is part of the standard procedure. In the case of this research one extra test, a so called isovolumetric contraction test, is carried out as a part of the urodynamics. Six weeks after the treatment patients will undergo another urodynamic investigation.
Before and six weeks after the treatment patients will fill out two questionnaires, taking 10-15 minutes of their time. After the post-operative urodynamics, patients will continue in the regular follow-up. The patients will not directly benefit from this study. However, for the patient group this study may provide information that predicts the need to start intermittent catheterisation after treatment with Botulinum toxin A.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Male and female patients 20 - 70 years of age
Symptoms of overactive bladder for more than 6 months
Micturition frequency > 7 times/day
Incontinence episodes > 6/week
Capable of filling out a micturition diary

Exclusion criteria

Treatment with Botulinum toxin A in the last 9 months
Treatment with anticholinergic drugs during the last 2 weeks
Active or repeated urinary tract infection
Peripheral neuropathy (i.e. Diabetic neuropathy)
Having an indwelling catheter
Malignancy in the area of the pelvis
Pelvic surgery less than 6 months ago

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2007
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	BOTOX®
Generic name:	Botulinum toxin A
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	11-09-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2007-004650-93-NL
CCMO	NL19281.042.07