

Botulinum toxin A intravesical injections in the treatment of Bladder Pain Syndrome/ Interstitial Cystitis.

Published: 18-02-2008

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To describe the course of symptoms of BPS/IC after intravesical injection of Botox®.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neuromuscular disorders
Study type	Interventional

Summary

ID

NL-OMON31587

Source

ToetsingOnline

Brief title

Bladder Pain Syndrome

Condition

- Neuromuscular disorders
- Bladder and bladder neck disorders (excl calculi)

Synonym

Bladder Pain Syndrome, Interstitial Cystitis

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W, onderzoeksbureau

Intervention

Keyword: Bladder Pain Syndrome, Botox®, Intravesical injections

Outcome measures

Primary outcome

The main parameter is the Visual Analog Scale (VAS) score as recorded by patient McGill Pain Questionnaire Dutch Language Version (MPQ-DLV).

Secondary outcome

The secondary parameters are the number of episodes of voiding as recorded by patient bladder diary and the quality of life as determined using the questionnaire Short Form-36 (SF-36).

Study description

Background summary

Bladder Pain Syndrome/Interstitial Cystitis (BPS/IC) is a syndrome characterized by bladder pain associated with urgency, frequency, nocturia, dysuria and sterile urine. The patho-physiology remains largely unclear. No universally, effective, treatment exists, and many patients do not respond to available therapies. When oral and intravesical conservative management of BPS/IC fails, various surgical techniques are available. All techniques, however, are invasive and irreversible.

Botulinum toxin-A (Botox®) inhibits the release of acetylcholine at the presynaptic cholinergic junction resulting in temporally muscle relaxation and bladder desensitisation. Recently, results of studies indicated Botox® injections are a safe and promising treatment modality for a variety of lower urinary tract dysfunctions. Three, relatively small, studies described the intravesical BTX-A injections in patients with BPS/IC. The results were not unequivocal. Here, we explore the effects of Botox® further with respect to treatment of BPS/IC.

Study objective

To describe the course of symptoms of BPS/IC after intravesical injection of Botox®.

Study design

A mono-center, non-placebo controlled, observational prospective study.

Intervention

Patients will receive 20 intravesical injections of botulinum toxin A, i.e. 200 U Botox® diluted in 20 ml 0,9% NaCl.

Study burden and risks

Subjects visit the clinic on screening day, treatment day and during three post-treatment visits. They fill out two questionnaires at each visit and a bladder diary covering the three days preceding a visit. The injection of Botox® be done under local anaesthesia at the outpatient department. Urinary retention, urinary tract infection, haematuria and influenza like complaints are adverse events we may expect following Botox® injections. Subjects benefit from participation by postponing invasive and irreversible surgery and, eventually replacing it completely, by the relatively less bothersome study intervention. The study intervention does not hamper subsequent surgical treatment, if necessary.

Contacts

Public

Vrije Universiteit Medisch Centrum

Boelelaan 1117
1081 HV Amsterdam
NL

Scientific

Vrije Universiteit Medisch Centrum

Boelelaan 1117
1081 HV Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Males and females aged 18 years, or older
- Subject has BPS/IC for a period of at least 9 months prior to screening, as determined by patient history:
 - patient had cystoscopy with hydrodistension and cold biopsy
 - patient has used oral medication: anticholinergic, NSAID and tricyclic antidepressant
 - patient has used intravesical instillations with cystistat, or ura-cyst, or bladder cocktails, or heparin, or oxybutinin
- Subject has Visual Analog Scale (VAS) more than 5
- Subject has daytime voiding frequency more than 7
- Subject has night-time voiding frequency more than 2
- Those subjects taking anticholinergic medication, NSAID or tricyclic antidepressant use a stable dose and they are willing to maintain the dose during the study
- Patients must be willing to use clean intermittent catheterization to empty the bladder

Exclusion criteria

- Patient is pregnant, or patients who want to become pregnant during the study
- Patient has an active urinary tract infection or recurrent urinary tract infections (> 5 urinary tract infections a year)
- Patient has a chronic or bacterial prostatitis
- Patient has a vaginitis
- Patient has an active sexually transmitted diseases
- Patient has urolithiasis
- Patient has an urethra or bladder diverticulum
- Patient has carcinoma of the uterus, cervix, vagina, urethra or prostate
- Patient has carcinoma in situ / malignancy of the bladder
- Patient has chemical-, tuberculous- or radiation cystitis
- Patient has hemophilia or other clotting factor deficiencies or disorders that cause bleeding diatheses.
- Patient has any medical condition that may put the patient at increased risk with exposure

to BTX-A including diagnosed myasthenia gravis, Eaton Lambert syndrome or amyotrophic lateral sclerosis

- Patient discontinued anticholinergic, NSAID or antidepressant medication for bladder pain < 14 days prior to screening
- Patient using intravesical instillations, or used it 4 weeks prior to screening
- Patient using neuromodulations devices for treatment of BPS/IC
- Patient is breastfeeding
- Patient has a post void residual volume above 200 ml
- Patients who will use neuromuscular blocking agents in the period of three days before until eight weeks after study treatment
- Patients who will use aminoglycoside antibiotics the period of three days before until eight weeks after study treatment

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-03-2008
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Botox®
Generic name:	Botulinum Toxin Type A
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date: 18-02-2008

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 22-02-2008

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 15-05-2008

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 26-05-2008

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 14-10-2008

Application type: Amendment

Review commission: METC Amsterdam UMC

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	EUCTR2007-005164-27-NL
CCMO	NL19744.029.07