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

Published: 18-02-2008
Last updated: 10-05-2024

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

urologie VU Medisch Centrum

## 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 dairy 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 |