

# A comparative study between treatment with oxybutynin and botulinum toxin type A in patients with neurogenic detrusor overactivity

<b>Submission date</b> 30/05/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/06/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 30/06/2017	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Traumatic spinal cord injury often causes neurogenic bladder dysfunction, where the patient is unable to control their bladder. Patients with neurogenic bladder dysfunction frequently struggle with urinary incontinence that may severely affect their quality of life. Oral anticholinergic medications such as oxybutynin have been widely used as a first-line treatment option for urinary incontinence. However, this class of medications does not work in some patients and may also cause side effects such as dry mouth, constipation, or blurred vision. Injections of botulinum toxin type A (BoNTA) into the bladder muscle has become a second-line option for patients who are unable to tolerate anticholinergic drugs or whose response to these drugs is unsatisfactory. BoNTA has proven effective at improving bladder function and quality of life. The aim of this study is to compare the effects of oral oxybutynin and BoNTA injections on the bladder function and quality of life of patients with bladder dysfunction resulting from spinal cord injury.

### Who can participate?

Patients aged over 18 who had had a spinal cord injury for at least 12 months and who have been regularly undergoing catheterisation for bladder dysfunction

### What does the study involve?

Participants are randomly allocated to be treated with either oral oxybutynin or BoNTA injections. Bladder function and quality of life are compared between the two groups.

### What are the possible benefits and risks of participating?

The risks to participants are the side effects of oxybutynin, such as dry mouth, constipation, or blurred vision, and rare generalised muscular weakness caused by BoNTA.

### Where is the study run from?

Dr Henrique Santillo Rehabilitation Center (Brazil)

When is the study starting and how long is it expected to run for?

April 2010 to November 2010

Who is funding the study?

Dr Henrique Santillo Rehabilitation Center (Brazil)

Who is the main contact?

Dr Ruiteir Silva Ferreira

## Contact information

### Type(s)

Scientific

### Contact name

Dr Ruiteir Silva Ferreira

### Contact details

Rua 1002, 700/301

Setor Pedro Ludovico

Goiania

Brazil

74820-150

## Additional identifiers

## Study information

### Scientific Title

A comparative study between oxybutynin and botulinum toxin type A in patients with neurogenic detrusor overactivity: urodynamic response and impact of treatment on quality of life: a randomised trial

### Acronym

BoNTA

### Study objectives

Botulinum toxin type A (BoNTA) injection into the detrusor muscle will result in improvement in urodynamic parameters, such as maximum cystometric capacity (MCC), maximum detrusor pressure (Pdetmax), and bladder compliance and on quality of life after 24 weeks when compared with oral oxybutynin in patients with detrusor overactivity (DO) resulting from spinal cord injury (SCI)

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics Board Committee Faculty of Medical Sciences of State University of Campinas (UNICAMP), 24/03/2010, ref: 0098.0.146.000-10

**Study design**

Randomised trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Spinal cord injury/detrusor overactivity

**Interventions**

1. Group 1 (n=40) will receive 15 mg oxybutynin orally three times daily
2. Group 2 (n=28) will be treated with intradetrusor injections of 300 U BoNTA (Botox)

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Botulinum toxin type A, oxybutynin

**Primary outcome(s)**

Evaluation of urodynamic parameters:

1. Maximum cystometric capacity (MCC)
2. Maximum detrusor pressure (Pdetmax)
3. Bladder compliance

**Key secondary outcome(s)**

1. Evaluation of quality of life
2. Systemic side-effects

**Completion date**

30/11/2010

**Eligibility****Key inclusion criteria**

1. Male and female patients
2. Over 18 years of age
3. Patients who have had an SCI for at least 12 months
4. Patients who have been regularly undergoing intermittent catheterisation

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Pregnancy
2. A desire to become pregnant during the study period
3. Breastfeeding
4. The use of anticoagulants or a report of a blood coagulation disorder
5. Neuromuscular transmission disorder
6. The use of any intravesical pharmacologic agents
7. Previous use of BoNTA

**Date of first enrolment**

01/04/2010

**Date of final enrolment**

30/11/2010

**Locations**

**Countries of recruitment**

Brazil

**Study participating centre**

Rua 1002, 700/301

Goiania

Brazil

74820-150

**Sponsor information**

**Organisation**

Dr Henrique Santillo Rehabilitation Center (Brazil)

**Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Dr Henrique Santillo Rehabilitation Center (Brazil)

**Results and Publications**

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration