ISRCTN56769820 https://doi.org/10.1186/ISRCTN56769820

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

Submission date
30/05/2011

Recruitment status
No longer recruiting

Registration date
13/06/2011

Overall study status
Completed

Last Edited
30/06/2017

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 Ruiter Silva Ferreira

Contact information

Type(s)
Scientific

Contact name
Dr Ruiter Silva Ferreira

Contact details
Rua 1002, 700/301
Setor Pedro Ludovico
Goiania
Brazil
74820-150

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure

Evaluation of urodynamic parameters:
1. Maximum cystometric capacity (MCC)
2. Maximum detrusor pressure (Pdetmax)
3. Bladder compliance

Secondary outcome measures
1. Evaluation of quality of life
2. Systemic side-effects

Overall study start date
01/04/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
68

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)

Sponsor details
Avenida Jose Monterio, 1655
Setor Negrao de LIma
Goiania
Brazil
74653-230

Sponsor type
Hospital/treatment centre

Website
http://www.crer.org.br/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Dr Henrique Santillo Rehabilitation Center (Brazil)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration