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The efficacy and safty of OnabotulinumtoxinA-Injection into the bladder in patients with neurogenic bladder dysfunction due to Parkinson's disease

Submission date
04/08/2016

Recruitment status
No longer recruiting

Registration date
10/08/2016

Overall study status
Completed

Last Edited
07/09/2016

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Parkinson’s disease (PD) is a common movement disorder, affecting approximately 120,000 people in the UK. It is a lifelong condition, which involves the gradual loss of nerve cells (neurons) in a part of the brain called the substantia nigra. These neurons are normally responsible for producing dopamine, a chemical messenger (neurotransmitter) which carries signals around the brain that help to coordinate movement. In people suffering from PD, these neurons gradually die over time, causing the level of dopamine in the brain to gradually fall. As the levels of dopamine become lower, the brain is unable to coordinate movement as effectively, causing abnormal movements such as stiffness, tremor (uncontrollable shaking) and slowness of movement (bradykinesia). Neurogenic detrusor overactivity (NDO), also known as overactive bladder, is a common complication of PD. It causes a range of symptoms, such as the need to urinate more frequently and/or urgently, the need to get up in the night to urinate and incontinence. It happens because damage to the nerves involved in bladder activity can lead to involuntary contractions (squeezing) of the bladder muscle leading to urinary leaking. Treating this can be difficult, as most of the available therapies do not work or cause significant side effects. OnabotulinumtoxinA (Botox) injections have been shown to be a well-tolerated, effective treatment for NDO. The aim of this study is to find out whether a single Botox injection could help alleviate NDO while still allowing patients to urinate when they want to.

Who can participate?
Adults with NDO caused by PD.

What does the study involve?
All participants are treated with a single 200 IU injection of OnabotulinumtoxinA into the detrusor muscle (muscle which forms a layer of the wall of the bladder) and a neuro-urological evaluation. The neuro-urological evaluation consists of having medical history taken, having an

ultrasound scan of the bladder and completing questionnaires about bladder function and quality of life. Four months later, the neuro-urological evaluation is repeated in order to find out whether the injection has led to improved bladder function and quality of life.

What are the possible benefits and risks of participating?
There is a chance that participants be benefit from an improvement in their bladder function following the Botox injection. There are no notable risks involved with participating.

Where is the study run from?
University Medical Centre Schleswig-Holstein (Germany)

When is the study starting and how long is it expected to run for?
April 2007 to December 2015

Who is funding the study?
University Medical Centre Schleswig-Holstein (Germany)

Who is the main contact?
Dr Stephanie C Knüpfer

Contact information

Type(s)
Scientific

Contact name
Dr Stephanie C. Knüpfer

Contact details
Department of Urology and Pediatric Urology
University Medical Centre Schleswig-Holstein
Campus Kiel
Arnold-Heller-Street 3
Kiel
Germany
24105

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Preserved micturition after intradetrusor onabotulinumtoxinA injection for treatment of neurogenic bladder dysfunction in Parkinson’s disease

Study objectives
200 IU OnabotulinumtoxinA injection would effectively alleviate the lower urinary tract dysfunction in the patient group and voluntary voiding would still be possible.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethikkommission Kiel AZ, 27/02/2013, ref: D416/13

Study design
Single-centre prospective non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Lower urinary tract dysfunction in parkinsonian disease

Interventions
All participants are treated with a single 200 IU injection of OnabotulinumtoxinA into the detrusor muscle distributed among 16-17 submucosal/ intradetrusor sites and 3-4 sites into the trigone. The injection was given gently and penetration of the detrusor muscle and thus injection into perivesical tissues was prevented.

At baseline and four months, participants undergo a neuro-urological evaluation, consisting of medical history, clinical examination, urine analysis, urinary tract ultrasound, urodynamic investigation, urethrocystoscopy and validated questionnaire contains 19 items on various aspects of quality of life. Urodynamics are performed according to good urodynamic practices as recommended by the International Continence Society (ICS). Patients are investigated in a sitting position. The bladder is filled with a room temperature mixture of 0.9% NaCL solution and contrast medium. The clinical examination includes digital rectal examination, vaginal inspection, and transrectal sonography.

Intervention Type

Drug

Phase
Not Applicable

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

Primary outcome measure
Urinary tract function (urinary frequency during daytime, night-time, urinary incontinence episode, post void volume) is measured using patient diaries at baseline and 4 months.

Secondary outcome measures
Quality of life is measured using the International Consultation and Incontinence Questionnaire - Lower Urinary Tract Symptoms Quality of Life at baseline and 4 months.

Overall study start date
01/04/2007

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. Patients with lower urinary tract dysfunction due to parkinsonian disease
2. Refractory to at least two different types oral antimuscarinics

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
A total of 10 patients

Key exclusion criteria
1. Unstable neurological disease.
2. Lower urinary tract malignancy
3. Previous onabotulinumtoxinA treatment
4. Untreated lower urinary tract obstruction
5. Missing informed consent

Date of first enrolment
20/04/2007

Date of final enrolment
18/06/2012

Locations

Countries of recruitment
Germany

Study participating centre
University Medical Centre Schleswig-Holstein
Department of Urology and Pediatric Urology
Campus Kiel
Arnold-Heller-Street 3
Kiel
Germany
24105

Sponsor information

Organisation
University Medical Centre Schleswig-Holstein

Sponsor details
Department of Urology
Arnold-Heller-Strasse 3
Kiel
Germany
24105

Sponsor type
Not defined

ROR
https://ror.org/01tvm6f46

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Schleswig-Holstein

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/10/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/09/2016		Yes	No