

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

<b>Submission date</b> 04/08/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/08/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/09/2016	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> 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?
<a href="#">Results article</a>	results	05/09/2016		Yes	No