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# Neuromodulation for reducing neurogenic detrusor overactivity in spinal cord injury

**Submission date**
26/06/2017

**Recruitment status**
No longer recruiting

**Registration date**
07/07/2017

**Overall study status**
Completed

**Last Edited**
01/10/2020

**Condition category**
Urological and Genital Diseases

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

## Plain English summary of protocol

Background and study aims
Following spinal cord injury, signals to between the brain and bladder are disrupted. This means that the voluntary control of the bladder stops functioning properly. Often as a result of this overactivity of the bladder muscle develops, leading to frequent contractions at low volumes. This may result in leaking urine and/or damage to the bladder and kidneys. Neuromodulation (a type of electrical stimulation) is a treatment which can alter nerve activity including those affecting the bladder. It is not currently known which nerve is the most effective to stimulate for improving continence in individuals with spinal cord injuries. The aim of pilot study is to determine to what extent neuromodulation can reduce unwanted bladder contractions and incontinence when delivered using skin surface electrodes over 4 different nerves in the body. The findings will inform the development of a new treatment method for bladder overactivity for people with spinal cord injuries.

Who can participate?
Adults aged 18 to 70 who have sustained a spinal cord injury more than 6 months ago and have subsequently developed bladder overactivity

What does the study involve?
Participation involves five separate sessions of urodynamics, during which a different nerve is stimulated in each session using surface 'sticker' electrodes. The stimulation involves electrodes on the genital nerve (penis or clitoris), the ankle, the lower back and the sacrum (triangular bone in the lower back), each tested separately. Before each session the participant may be asked to stop taking their current bladder suppressing medication for five days. Urodynamics involves catheters being inserted into the bladder through the urethra and into the rectum, these fill the bladder with sterile water and measure pressures to determine overactivity. The participants have their bladders filled without stimulation and with stimulation, to assess each nerve's effect on bladder activity. Each session takes around two hours and takes place on a separate day.

What are the possible benefits and risks of participating?
There are no notable benefits with participating. There are a few potential risks including urinary

tract infections (infections of the bladder, kidneys and connecting tubes), incontinence (unintentionally passing urine), autonomic dysreflexia (dangerous rise in blood pressure), and skin irritation from the electrodes.

Where is the study run from?
This study is being run by the Royal National Orthopaedic Hospital in Stanmore, London in collaboration with University College London. All investigations will take place in the London Spinal Cord Injuries Centre's urodynamics clinic.

When is the study starting and how long is it expected to run for?
September 2015 to September 2019

Who is funding the study?
The INSPIRE Foundation (UK)

Who is the main contact?
1. Mr Sean Doherty (public)
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# Contact information

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# Additional identifiers

### Protocol serial number
20733

# Study information

### Scientific Title
Investigating transcutaneous neuromodulation for reduction of bladder, bowel and spasticity in spinal cord injury as an alternative to pharmacological treatment: towards wearable devices

### Study objectives
The aim of this research is to investigate the acute effects of neuromodulation (electrical stimulation of neural pathways to modify their activity) on bladder spasticity with respect to stimulation site, to determine the optimum anatomical site for reduction of bladder overactivity in patients with Spinal Cord Injury (SCI).

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Queen Square REC London, 28/01/2016, ref: 16/LO/0164

### Primary study design
Interventional

### Study design
Randomised; Interventional; Design type: Treatment, Device

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Specialty: Renal disorders, Primary sub-specialty: Renal disorders

### Interventions
To ascertain the most effective transcutaneous stimulation site the efficacy of neuromodulation using surface electrodes is investigated at distinct anatomical sites: Dorsal Genital Nerve, Posterior Tibial Nerve, Sacral Roots and Spinal Cord.

The investigation involves the monitoring of the bladder activity and pressures during standard urodynamics performed both with and without stimulation in up to 20 participants. First a standard cystometrogram (CMG) is performed to measure bladder capacity and activity before any stimulation takes place.

Electrodes are then be placed on the skin over one of the four sites (a different one each session) and the stimulation intensity is set. Next further CMG are performed, during which stimulation is started each time the pressure in the bladder rises as a result of unwanted contractions. The CMG's involves catheters being inserted into the bladder through the urethra and into the rectum, these fill the bladder with sterile water and measure pressures to determine overactivity.

The investigation takes place over five sessions on separate days, each takes up to two hours and each assesses one stimulation site.

### Intervention Type
Other

### Primary outcome(s)
Bladder overactivity is measured using standard urodynamics to measure bladder pressures and volumes without stimulation present (control), then with stimulation over one of four sites (experimental).

### Key secondary outcome(s)
No secondary outcome measures

### Completion date
13/09/2019

## Eligibility

### Key inclusion criteria
1. Spinal Cord Injured
2. Aged 18-70
3. Male or Female
4. Injury sustained >6 months ago
5. Urodynamically proven Neurogenic Detrusor Overactivity

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

**Upper age limit**
70 Years

**Sex**
All

**Total final enrolment**
10

**Key exclusion criteria**
1. Recipient of intra-detrusor botulinum toxin injections within the last 6 months
2. Previous surgical intervention on bladder/sphincters
3. Showing positive leucocytes and nitrites on urinalysis on the day of investigation
4. Pregnancy

**Date of first enrolment**
04/04/2016

**Date of final enrolment**
14/09/2018

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Royal National Orthopaedic Hospital (RNOH)**
Brockley Hill
Stanmore
London
United Kingdom
HA7 4LP

# Sponsor information

**Organisation**
Royal National Orthopaedic Hospital NHS Trust

**ROR**
https://ror.org/03dx46b94

# Funder(s)

### Funder type
Government

### Funder Name
Inspire Foundation

### Alternative Name(s)
inspirefoundationuk, inspirefndtn, The INSPIRE Foundation, INSPIRE

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Trusts, charities, foundations (both public and private)

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary
Data sharing statement to be made available at a later date

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 17/12/2019 | 01/10/2020 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |