ISRCTN99373118 https://doi.org/10.1186/ISRCTN99373118

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)
sean.doherty.15@ucl.ac.uk
2. Dr Sarah Knight (scientific)
sarah.knight@rnoh.nhs.uk

Contact information

Type(s)
Public

Contact name
Mr Sean Doherty

Contact details
Royal National Orthopaedic Hospital
Brockley Hill
Stanmore
London
United Kingdom
HA74LP
+44 (0)207 909 5605
sean.doherty.15@ucl.ac.uk

Type(s)
Scientific

Contact name
Dr Sarah Knight

ORCID ID
https://orcid.org/0000-0002-5994-2081

Contact details
Royal National Orthopaedic Hospital
Brockley Hill

Stanmore
London
United Kingdom
HA74LP
+44 (0)207 909 5605
Sarah.knight@rnoh.nhs.uk

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