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Non-invasive neuromodulation for bladder suppression following spinal cord injury

Submission date	Recruitment status	[X] Prospectively registered
21/08/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/08/2017	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/12/2018	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Spinal cord injury disrupts signals between the brain and the rest of the body, including the signals needed to voluntarily control the bladder and bowels. Following this loss in control people often experience bladder overactivity and incontinence. Currently the main treatment for this is medication, which can have side effects. Neuromodulation (a type of electrical stimulation) is a treatment which can alter nerve activity including that affecting the bladder. The aim of this study is to find out to what extent neuromodulation can reduce unwanted bladder contractions and incontinence when delivered using skin surface electrodes and a portable stimulator in people with spinal cord injury and bladder overactivity over a week in their home environment.

Who can participate?
Spinal cord injured patients aged 18 and over with overactive bladder

What does the study involve?
Participants first record a bladder diary on a provided device for one week. They then visit the clinic to test the portable stimulation system whilst their bladder's behaviour is measured, to ensure they can safely apply it by themselves and to record initial effectiveness. They use the stimulation to manage overactivity at home for one week, then visit the clinic again to re-assess its effect whilst recording bladder behaviour.

What are the possible benefits and risks of participating?
There are no direct benefits of participating. There are a few potential risks including urinary tract infections (infections of the bladder, kidneys and connecting tubes), autonomic dysreflexia (dangerous rise in blood pressure), and skin irritation from the electrodes. These risks are discussed and monitored closely during the study.

Where is the study run from?
Royal National Orthopaedic Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2016 to September 2020

Who is funding the study?
Inspire Foundation (UK)

Who is the main contact?
Mr Sean Doherty
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Contact information

Type(s)
Public

Contact name
Mr Sean Doherty

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
34995

Study information

Scientific Title
NEUROMOD: Researching the effect of electrical stimulation on bladder overactivity following spinal cord injury in a home pilot study

Acronym
NEUROMOD

Study objectives

The purpose of this pilot study is to determine to what extent neuromodulation can reduce unwanted bladder contractions and incontinence when delivered using skin surface electrodes and a portable stimulator in people with spinal cord injury and bladder overactivity over a week in their home environment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Stanmore – London REC, 08/08/2017, ref: 17/LO/1031

Study design
Non-randomised; Interventional; Design type: Treatment, Device, Complementary Therapy

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

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
UKCRC code/ Disease: Injuries and Accidents/ Injuries to unspecified part of trunk, limb or body region, Renal and Urogenital/ Other disorders of the genitourinary system

Interventions
Participants will first record a bladder diary on a provided device for one week. They will then visit the clinic to test the portable stimulation system whilst their bladder's behaviour is measured, this will be to ensure they can safely apply it by themselves and to record initial effectiveness. They will use the stimulation to manage overactivity at home for one week, then repeat the visit to the clinic to re-assess its effect whilst recording bladder behaviour.

Intervention Type
Device

Primary outcome measure
Bladder overactivity, measured using bladder diary; Timepoint(s): 7 days without intervention, the 7 days with intervention

Secondary outcome measures

Effect of neuromodulation on bladder overactivity, measured using ambulatory urodynamics conducted at the beginning and at the end of the 7-day period where participants are using the stimulation device

Overall study start date
14/09/2016

Completion date
01/09/2020

Eligibility

Key inclusion criteria
1. Spinal cord injured
2. Aged 18 and over
3. Male or female
4. Injury sustained >6 months ago
5. Urodynamically proven neurogenic detrusor overactivity

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 12; UK Sample Size: 12

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
5. Cardiac pacemaker
6. Active sepsis
7. History of significant Autonomic Dysreflexia
8. Poorly controlled epilepsy. Acceptable where epilepsy is controlled by drugs or there have been no fits experienced for a reasonable period
9. Patients with a cancerous tumour in the area of the electrical stimulation will be excluded as increased local blood flow may increase tumour growth
10. Patients with exposed orthopaedic metal work in the area of electrical stimulation

Date of first enrolment

31/08/2017

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal National Orthopaedic Hospital
Brockley Hill
Stanmore
United Kingdom
HA7 4LP

Sponsor information

Organisation
Royal National Orthopaedic Hospital NHS Trust

Sponsor details
Brockley Hill
Stanmore
London
England
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03dx46b94

Funder(s)

Funder type
Charity

Funder Name
Inspire Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in relevant peer-reviewed journal, submission of manuscript by September 2020.

Intention to publish date
01/09/2020

Individual participant data (IPD) sharing plan
The 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?
HRA research summary			28/06/2023	No	No