

Volitional control of the pelvic floor in incomplete spinal cord injury

Submission date 29/09/2006	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 29/09/2006	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 08/08/2016	Condition category Urological and Genital Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0209178291

Study information

Scientific Title
Volitional control of the pelvic floor in incomplete spinal cord injury

Study objectives

This proposal is for a pilot study to determine the extent of residual voluntary control over the pelvic floor muscles and to investigate the training effects of these muscles on changes in strength of the pelvic sphincters and involuntary contractions of the urinary bladder in incomplete spinal cord injury. A positive outcome from this study will be used to establish funding for a broader based programme of research.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Urological and Genital Diseases

Interventions

Single randomised within-subject cross-over study in comparing the interventional effects of volitional pelvic floor muscle training (PFMT) with our standard dorsal penile nerve (DPN) electrical stimulation techniques (neuromodulation) on bladder and sphincter function in male patients with an incomplete spinal cord injury. Randomisation of intervention will help to ensure control of order effect. The principal measures will be the percentage inhibition on neurogenic detrusor overactivity, percentage changes in bladder capacity and percentage changes in sphincter strength and dyssynergia.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Extent of residual voluntary control over the pelvic floor muscles.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/04/2006

Eligibility

Key inclusion criteria

Subjects with in incomplete spinal cord injury.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/07/2005

Date of final enrolment

01/04/2006

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

RNOHT

Stanmore

United Kingdom

HA7 4LP

Sponsor information**Organisation**

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type

Government

Funder Name

Royal National Orthopaedic Hospital NHS Trust (UK) NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration