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Volitional control of the pelvic floor in incomplete spinal cord injury

Submission date	Recruitment status	[_] Prospectively registered
29/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/08/2016	Urological and Genital Diseases	[_] 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

Study design
Randomised controlled trial

Primary study design
Interventional

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