

# Volitional control of the pelvic floor in incomplete spinal cord injury

<b>Submission date</b> 29/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 08/08/2016	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Not Specified

## Participant information sheet

## 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 measure**

Extent of residual voluntary control over the pelvic floor muscles.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/07/2005

**Completion date**

01/04/2006

**Eligibility****Key inclusion criteria**

Subjects with in incomplete spinal cord injury.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

Not provided at time of registration

**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**

England

United Kingdom

**Study participating centre**  
RNOHT  
Stanmore  
United Kingdom  
HA7 4LP

## **Sponsor information**

### **Organisation**

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

### **Sponsor details**

The Department of Health, Richmond House, 79 Whitehall  
London  
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+44 (0)20 7307 2622  
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### **Sponsor type**

Government

### **Website**

<http://www.dh.gov.uk/Home/fs/en>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

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

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

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

**IPD sharing plan summary**

Not provided at time of registration