

Spinal cord stimulation for the treatment of central pain in Multiple Sclerosis

Submission date 23/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/01/2018	Condition category Nervous System 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
4891

Study information

Scientific Title

Comparison of spinal cord stimulation and the clinical and quantitative sensory testing response in patients with MS pain versus patients with peripheral nerve injury pain

Study objectives

We are measuring the effect of spinal cord stimulation on central pain in Multiple Sclerosis (MS), comparing the clinical and Quantitative Sensory Testing response in patients with MS pain and those with peripheral nerve injury pain. We hypothesise that MS pain patients will have a different sensory profile to peripheral nerve injury pain patients. We also hypothesise that spinal cord stimulation will benefit most of the peripheral nerve injury patients and some of the MS pain patients. We are collecting Quantitative Sensory Testing measurements from an age- and gender-matched group of healthy volunteers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Sefton LREC, 08/08/2008, ref: 08/H1001/103

Study design

Non-randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Neurological; Subtopic: Neurological (all Subtopics); Disease: Nervous system disorders

Interventions

Trial of spinal cord stimulation. A temporary electrode is inserted into the epidural space and attached to an external radiofrequency transmitter, which when switched on gives a pleasant paraesthesia in the area of pain. This stimulator remains in situ for 7 days. Pain diaries are kept throughout the trial and Quantitative Sensory Testing is completed once with stimulation and once without, with the tester blinded.

Follow up length: 2 months

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Changes in pain scores measured by daily pain diaries, measured on day 7 of the trial

Secondary outcome measures

Comparison of QST measurements in MS patients with and without stimulation, measured on day 5 of the trial, when the second sensory testing is complete

Overall study start date

01/07/2008

Completion date

30/06/2010

Eligibility

Key inclusion criteria

1. Group 1: Confirmed MS with central pain
2. Group 2: Peripheral nerve injury pain
3. Both groups eligible for spinal cord stimulation
4. Group 3: Age- and gender-matched healthy controls
5. Male and female, aged 18 years or older

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 302) MS central neuropathic pain3) Peripheral nerve injury pain

Key exclusion criteria

1. Unsuitable for spinal cord stimulation
2. High intake of opiates
3. High levels of psychological distress

Date of first enrolment

01/07/2008

Date of final enrolment

30/06/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Pain Research Institute

Liverpool

United Kingdom

L9 7AL

Sponsor information

Organisation

Walton Centre for Neurology and Neurosurgery (UK)

Sponsor details

Division of Neurological Science

Clinical Sciences Centre for Research and Education

Lower Lane

Liverpool

England

United Kingdom

L9 7LJ

Sponsor type

Hospital/treatment centre

Website

<http://www.thewaltoncentre.nhs.uk/>

ROR

<https://ror.org/05cvxat96>

Funder(s)

Funder type

Charity

Funder Name

Multiple Sclerosis Society (UK)

Alternative Name(s)

Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society UK, Multiple Sclerosis Society UK, MS Society

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

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