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

Submission date	Recruitment status	[ ] Prospectively registered
23/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/01/2018	Nervous System 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
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

Study type(s)
Treatment

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 eipdural 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(s)
Changes in pain scores measured by daily pain diaries, measured on day 7 of the trial

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
Pain Research Institute
Liverpool
United Kingdom
L9 7AL

Sponsor information

Organisation
Walton Centre for Neurology and Neurosurgery (UK)

ROR
https://ror.org/05cvxat96

Funder(s)

Funder type
Charity

Funder Name
Multiple Sclerosis Society (UK)

Alternative Name(s)
mssocietyuk, MS Society UK, Multiple Sclerosis Society UK, Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration