

The effect of spinal cord stimulation (SCS) on allodynia in patients with neuropathic pain

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/04/2015	Condition category Signs and Symptoms	<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
N0259139017

Study information

Scientific Title

The effect of spinal cord stimulation (SCS) on allodynia in patients with neuropathic pain

Study objectives

This study is designed to answer this research question: does spinal cord stimulation (SCS) reduce the intensity and area of mechanical and thermal allodynia in patients with neuropathic pain? It is a single-centre study, involving 25 patients, with neuropathic pain, of peripheral origin, and associated with mechanical and thermal allodynia (touch and heat/cold induced pain, respectively). While SCS is considered standard treatment for refractory neuropathic pain, only a few controlled studies have been published on its efficacy, and none systematically assessing allodynia. Our aim is to select patients with mechanical allodynia (most of whom have cold allodynia as well) and measure allodynia before, during and after stimulation to study this aspect further.

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)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Signs and Symptoms: Allodynia

Interventions

We will recruit 25 patients with mechanical allodynia and neuropathic pain for this study. Patients are those in whom the clinical decision has been made either to (a) carry out a trial SCS, or (b) implant a permanent stimulator after the trial has been successful. In all these cases, due to clinical situation and routine testing, patients will spend some time without stimulation. We use this opportunity to compare the effect of stimulation on allodynia and pain in these patients. Measurements for intensity and area allodynia (using a brush, a 16 g or 26 g von Frey filament, thermal rollers and thermal stimulator applied to the skin) will be carried out with the stimulator ON and OFF. The level of pain during the two phases will be recorded as well. The

patient will attend twice, once when on arrival the stimulator is switched off and a second time when on arrival the stimulator is switched on. The order of ON and OFF will be randomised, and allodynia's always tested during both ON and OFF periods.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2004

Completion date

01/03/2005

Eligibility**Key inclusion criteria**

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

25

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/04/2004

Date of final enrolment

01/03/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

The Walton Centre for Neurology and Neurosurgery

Liverpool

United Kingdom

L9 7LJ

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

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

Funder(s)

Funder type

Government

Funder Name

The Walton Centre for Neurology and Neurosurgery NHS Trust (UK)

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