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

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 17/04/2015	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] 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 allodynias 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