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External peripheral neuromodulation for the relief of chronic pain

Submission date	Recruitment status	[ ] Prospectively registered
05/08/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/02/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/07/2016	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RJ1 09/N084

Study information

Scientific Title
A randomised controlled feasibility trial of external peripheral neuromodulation in the treatment of intractable localised chronic neuropathic pain

Study objectives
The study hypothesis is that, when given over three treatment sessions at weekly intervals, external peripheral neuromodulation will reduce pain severity at 7 days after the final treatment in patients with intractable localised chronic pain with predominantly neuropathic features.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Guy's Research Ethics Committee, 22/04/2009, ref: 09-H0804-46

Study design
Single centre double-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
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
Chronic neuropathic pain

Interventions
Three 5-minute treatment sessions of external peripheral neuromodulation at 2 Hz (or sham stimulation) at weekly intervals. Follow-up to 7 days after the last session, i.e. 21 days.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Visual Analogue Score (VAS) of pain severity one week following third (final) neuromodulation session.

Secondary outcome measures
1. VAS of pain severity immediately after treatment and at 7 day intervals to end of study (i.e., days 7, 14 and 21)
2. VAS of pain severity at shorter intervals of less than a week
3. Numerical rating scores (NRS) of:
3.1. Sleep quality
3.2. Functional impact
3.3. Emotional impact
Measured at 7 days following third (final) neuromodulation session.
4. Numerical rating scores on Pain Self-Efficacy Questionnaire (PSEQ) at 7 days following third (final) neuromodulation session
5. Changes in medication usage
6. Change in size of painful area on pain/paraesthesiae map

Overall study start date
17/08/2009

Completion date
16/08/2010

Eligibility

Key inclusion criteria
1. Patient age is 18 years or older, either sex
2. Patient has chronic neuropathic (or predominantly neuropathic) intractable pain
3. Patient has an area of pain with a typical dermatomal distribution that can be expected to be covered with a single episode of local stimulation
5. In the opinion of the Investigator and the patient's consultant, all standard medical options have been tried without sufficient improvement in pain control (including opioids, nerve blocks, etc.)
6. Patient has a Visual Analogue Scale (VAS) pain score of 5 cm (or greater) on a 10 cm line

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Patient has a history of substance abuse or substance dependency in the past 6 months prior to baseline data collection

2. Patient is currently participating in another clinical study
3. Patient lacks capacity for informed consent to the trial in the view of person taking consent and/or investigators
4. Pregnancy - if the painful area lies within 50 cm of the gravid uterus
5. Patient has difficulties in adequate understanding of English for consent, clinical review and self-completion questionnaires
6. Patient does not permit notification to General Practitioner of enrolment in the study
7. Patient has previous experience of peripheral neuromodulation. Note that prior transcutaneous electrical nerve stimulation (TENS) experience is permitted.

Date of first enrolment
17/08/2009

Date of final enrolment
16/08/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Pain Management & Neuromodulation Centre
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust (UK)

Sponsor details
Research & Development
3rd Floor Conybeare House
Guy's Hospital
St Thomas Street
London
England
United Kingdom
SE1 9RT

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Government

Funder Name
Guy's and St Thomas' NHS Foundation 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