ISRCTN07743794 https://doi.org/10.1186/ISRCTN07743794

External peripheral neuromodulation for the relief of chronic pain

Submission date
05/08/2009

Registration date
18/02/2010

Last Edited
18/07/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Single centre double-blind randomised controlled trial

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

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

Sponsor information

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration