# External peripheral neuromodulation for the relief of chronic pain

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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

#### Contact name

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#### Contact details

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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

#### Study design

Single centre double-blind randomised controlled trial

#### Primary study design

Interventional

#### 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

# 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

#### Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 11/11/2025 No

Yes