

# External peripheral neuromodulation for the relief of chronic pain

<b>Submission date</b> 05/08/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/02/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/07/2016	<b>Condition category</b> Nervous System Diseases	<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

### Contact name

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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 impactMeasured 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