

Transcutaneous electrical nerve stimulation (TENS) for patients with upper limb complex regional pain syndrome: a feasibility study

Submission date 04/11/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/12/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 09/11/2016	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Transcutaneous Electrical Nerve Stimulation (TENS) could be considered as a treatment for pain syndrome. Theoretical evidence supports this. However, this is not studied in detail. Also, our discussions with doctors have found that that patients are unlikely to tolerate having adhesive pads (that are used in TENS) attached to the painful site. To overcome that practical barrier TENS could be applied through pads placed above, or near the affected area, and as such, could be offered to patients for home-use. Therefore this study aims to address the practical issues and the evidence gap.

Who can participate?

Adult patients attending the participating pain clinic who have type 1 CRPS of the upper limb for 6 months or more can participate in the study.

What does the study involve?

Participants with pain syndrome will be randomly allocated to an intervention or a placebo (dummy) group. The intervention group will self-administer TENS daily for a minimum of three weeks. The placebo group will receive a dummy (over the same time frame). Pain relief, usage of pain medication, function, indirect measures of limb's mental body image will be measured before treatment, immediately after treatment and 3 months thereafter. On completion of treatment all participants will undergo exit interviews. All data collection will be carried out by the clinical researcher giving the intervention.

What are the possible benefits and risks of participating?

There are no direct benefits to taking part in this study, though all participants who complete this study will receive a £20 voucher. The risks of taking part in this study are considered to be minimal in that they are unlikely to occur and the consequence would likely be minor. The risks associated with using TENS are skin irritation and electric shock. Skin irritation including reddening beneath or around the electrodes can occur.

Where is the study run from?

The study is run from the Pain Clinic at James Cook University Hospital in Middlesbrough, UK in collaboration with Teesside University (UK), Leeds Metropolitan University (UK), The University of Applied Sciences, Bochum, Germany and the Ruhr University, Bochum, Germany.

When is the study starting and how long is it expected to run for?

The study will begin in November 2013 and is expected to run for 2 years finishing in December 2015. Recruitment will end in September 2015.

Who is funding the study?

The study is being funded by the British Association of Hand Therapists (BAHT), UK.

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Transcutaneous electrical nerve stimulation (TENS) for patients with upper limb complex regional pain syndrome: a pilot randomised controlled trial

Study objectives

There will be a statistically significant difference in pain, function and perception between the TENS group and the placebo TENS group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Teesside University School of Health and Social Care Research Governance and Ethics committee, 30/07/2013, ref: 106/13
2. NHS NREC North East - York, 23/10/2013, ref: 13/NE/0286

Study design

Two groups feasibility study consisting of a single-blind placebo-controlled design

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

Complex Regional Pain Syndrome

Interventions

Participants with complex regional pain syndrome (CRPS) will be randomised into two groups:

1. Intervention

The intervention group will self-administer TENS daily over a minimum of three weeks. TENS, in this study, involves the electrical stimulation of the upper limb proximal to the affected area. It will be delivered using a commercially available two-channel TENS unit. During the first physiotherapy session the device will be provided to the patient along with a detailed demonstration with the research physiotherapist where the patient will be thought how to apply the TENS themselves. They will also be provided with a simple instruction sheet to facilitate home use. Pulsed, synchronised dual channel TENS will then be self-administered (for 90 minutes) at home, daily, over a period of 3 weeks. The prescribed stimulation pattern will be: 20 pulses delivered over a 1 second period (20 Hz stimulation frequency) with a non-stimulation interval of 5 seconds. However, this prescription can be tailored by the participant and therapist to find the dose which is most suitable for the participant.

2. Placebo:

The placebo group will receive a sham TENS protocol (over the same time frame)

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Pain

Pain will be measured using a simple pain Visual Analogue Scale (VAS) with patients asked to rate the pain in their affected limb using the following statement 'How would you rate your average pain over the last two days' with anchor statements of 'no pain' and 'worst imaginable pain'. The VAS will be collected at baseline, post treatment and at the 3-month follow-up. Patients will also be asked to keep a pain diary where they rate their pain on a numerical rating scale (0-10) four times (morning, afternoon, evening and night) each day using the following statement 'How would you rate your pain at this point in time' with anchor statements of 'no pain' and 'worst imaginable pain'.

2. Pain Medication Use

Participants will monitor their daily medication use in a diary over the course of the study. Participants will be asked to record for each day if pain medication for the CRPS pain was used, and if so what type of medication and what dosage (number of pills and size [mg] of pills).

3. Function

Function will be assessed using the Disabilities of the Arm, Shoulder and Hand test (DASH), a 30-item questionnaire that is scaled from 0-100. It asks the patient about their ability to perform various daily tasks on a 0-5 Likert scale, which is then transposed onto a 0-100 scale

4. Hand Laterality Recognition Task

Correctly identifying the laterality (i.e. 'left' or 'right') of an image depicting a hand requires the participant to engage in the mental rotation (motor imagery) of their own limbs, with optimal performance relying on an intact body schema. Participants will be assessed using a version of this 'Hand Laterality Recognition Task' (HLRT). They will be presented with images of hands on a computer screen that vary in their laterality, view, orientation and rotation; and asked to respond as quickly and as accurately as possible (by pressing one of two keys on a computer keyboard). Presentation of stimuli (images) and resulting data (accuracy and response time) will be controlled and logged using customized software (E-Prime, www.pstnet.com).

5. Bath CRPS Body Perception Disturbances (BPD)

The BPD is a questionnaire which assesses a patients' perception of their affected limb. Participants rate different aspects of perception such as feelings of ownership and attention. Five of the items are on a 0-10 scale, two of the items are yes/no answers and the final item is graded on a 0-1-2 scale. A total score is scaled from 0-57. Higher scores denote poorer perception of the limb.

The primary outcomes will be measured at baseline, three weeks and three months.

Secondary outcome measures

1. Placebo/blinding credibility

To investigate the appropriateness of the single-blinding procedures the participants will be asked to make a judgement (at the 3-month follow-up by the treating clinician RK) as to which group they were randomised to. The blinding assessment method will ask the participants two questions. The first question 'do you believe your TENS unit was functioning properly?' has five

possible responses:

1. I am certain my TENS unit was working properly
2. I think my TENS unit was probably working properly
3. I have absolutely no idea whether the TENS unit was working properly or not
4. I think my TENS unit was probably not working properly
5. I am certain my TENS unit was not working properly

The second question will ask 'If above you answered '3) I have absolutely no idea whether the TENS unit was working properly or not' what would you guess':

1. Functioning properly
2. Not functioning properly

This assessment method has been previously used previously by MJ and others in the TENS field.

2. Adverse reactions

If any participant reports an adverse reaction this will be recorded on an adverse reaction recording form designed by the Teesside University research and ethics board, which records severity, relationship to the intervention, action taken and outcome at date ceased.

3. Recruitment/eligibility

The number of participants recruited into the study over the 20-month period will be used to judge the recruitment rate. Additionally the number of participants invited to take part but not meeting the eligibility criteria on formal screening will be recorded to assess the eligibility criteria.

4. Qualitative interviews

All participants will undertake an exit interview at the three-month point. At this point patients' perceptions of the intervention in relation to objectives 1 and 2 will be asked. A semi-structured interview approach will be used. The interviews (<20 minutes) will be audio-recorded and transcripts typed out verbatim. The interviews will be analysed using thematic analysis. The interview topic guide for the questions will be as follows:

1. What were your general impressions of the treatment?
2. What were your expectations of treatment and to what degree do you feel these expectations were met?
3. What is your opinion of the usability and acceptability of the intervention/placebo?
4. What is your opinion about using this intervention in the future?
5. Is there anything else you would like to say about the intervention/study?

The following prompt questions will be used at appropriate times within the interview: why? why not?, can you give me an example? At the beginning and end of the study participants will be asked to rate the following:

- A. How helpful do you believe TENS will be for your pain on a 0-10 scale: 0 = not at all helpful 10 = extremely helpful
- B. How helpful do you believe sub-threshold TENS will be for your pain on a 0-10 scale: 0 = not at all helpful 10 = extremely helpful
- C. How easy to use do you think TENS will be: 0 = not at all easy to use 10 = extremely easy to use.

The secondary outcomes will be measured at baseline, three weeks and three months.

Overall study start date

10/11/2013

Completion date

31/12/2015

Eligibility

Key inclusion criteria

1. 18+ years of age
2. Have had complex regional pain syndrome for ≥ 6 months
3. Can speak English to a good standard
4. No neurological conditions
5. Capable of making an informed decision to take part or not

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

30

Key exclusion criteria

1. Individuals with a pacemaker, heart disease or epilepsy
2. Individuals who are pregnant
3. Abnormal skin sensation in the area below the electrodes

Date of first enrolment

10/11/2013

Date of final enrolment

01/09/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Teesside University
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Sponsor information

Organisation

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Funder(s)

Funder type

Charity

Funder Name

British Association of Hand Therapists (BAHT) (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/11/2016		Yes	No
HRA research summary			28/06/2023	No	No