

Transcutaneous Electrical Nerve Stimulation in the management of cancer bone pain II: a two-arm, crossover, prospective, randomised, controlled, external pilot study for patients with cancer bone pain

Submission date 05/07/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/10/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-to-see-if-a-nerve-stimulating-machine-called-tens-can-control-bone-cancer-pain>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

2007-003902-84

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Transcutaneous Electrical Nerve Stimulation in the management of cancer bone pain II: a two-arm, crossover, prospective, randomised, controlled, external pilot study for patients with cancer bone pain

Acronym

TENS FEASIBILITY

Study objectives

1. Does Transcutaneous Electrical Nerve Stimulation (TENS) have analgesic benefits in people with cancer bone pain?
2. In people with cancer bone pain, does TENS produce analgesic benefits at rest, on movement or both?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leeds (west) Research Ethics Committee on 28/03/2007 (REC ref: 07/Q1205/5)

Study design

Two-arm, crossover, prospective, randomised, controlled, external pilot study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cancer bone pain

Interventions

Active TENS versus placebo TENS.

Patients will be randomised to receive either active or sham TENS at site of pain for one hour. They will then receive the other in a second treatment. Patients and research nurses will be blinded. There are two treatment sessions each lasting 1.5 hours, the treatment sessions are separated by a minimum of 48 hours. The follow-up session is performed over the telephone 48 hours after the final treatment session.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Pain at rest one hour after starting TENS application
2. Pain at movement one hour after starting TENS application

Secondary outcome measures

1. Recruitment and screening of patients to determine recruitment strategy for the phase III clinical trial: the timepoint measurement of this outcome is continuous; as it is a feasibility study we need to look at the barriers (if any) to palliative care research. A detailed screening and enrolment log is maintained for this purpose
2. Optimal electrode placement: this measurement will be performed at each treatment visit following the baseline assessment
3. Patients experience: this will be assessed at the end of each treatment period following 60 minutes of TENS treatment
4. Toxicity: this will be assessed throughout each treatment session and again at the follow up telephone review

Overall study start date

04/06/2007

Completion date

01/12/2007

Eligibility

Key inclusion criteria

Patients who:

1. Have a radiologically evident bone metastasis
2. Experience pain from a bone metastasis that affects their activities of daily living (e.g., transferring from sitting to standing, bending over, walking or dressing upper body)
3. Experience pain that is rated at least 3 out of 10 on a numerical pain intensity rating scale at rest or on movement on first visit
4. Are aged 18 years or over
5. Have provided written informed consent and are willing to attend St Gemmas Hospice for study periods
6. Are willing and able to complete patient assessments and pain scores
7. In the opinion of the investigator the patient will derive potential benefit from the use of TENS
8. Have an estimated survival of longer than four weeks

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

38

Key exclusion criteria

Patients who:

1. Are unable to complete patient related information on entry
2. Do not have ongoing cancer
3. Are unable to provide informed consent (for physical or psychiatric reasons)
4. Are not suitable for TENS as described by the Chartered Society of Physiotherapy (CSP) Standards for the Use of Electrophysical Modalities. This includes patients fitted with pacemakers and patients who are pregnant or have epilepsy. Patients with abnormal sensation over the site of pain will also be excluded under CSP criteria
5. Have had changes to opioid analgesic medication (increase or decrease in opioid dose of 30%, addition or removal of opioid) within 48 hours prior to baseline assessment
6. Have received TENS within the previous four weeks

Date of first enrolment

04/06/2007

Date of final enrolment

01/12/2007

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

St Gemma's Hospice

Leeds

United Kingdom

LS17 6QD

Sponsor information

Organisation

University of Leeds (UK)

Sponsor details

Room 7.11, Level 7
Worsley Building
Clarendon Way
Leeds
England
United Kingdom
LS2 9NL

Sponsor type

University/education

Website

<http://www.leeds.ac.uk/>

ROR

<https://ror.org/024mrx33>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (UK) (ref: C18324/A7715)

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

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?
Plain English results				No	Yes
Results article	results	01/04/2010		Yes	No