ISRCTN92118149 https://doi.org/10.1186/ISRCTN92118149

# 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**<br>05/07/2007 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>03/10/2007 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited**<br>26/10/2018 | **Condition category**<br>Cancer | [_] 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**
Dr Mike Bennett

**Contact details**
St Gemma's Hospice
329 Harrogate Road
Leeds
United Kingdom
LS17 6QD
+44 (0)113 218 5500
m.bennett@st-gemma.co.uk

## Additional identifiers

**Clinical Trials Information System (CTIS)**
2007-003902-84

# 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)

### Primary study design
Interventional

### Study design
Two-arm, crossover, prospective, randomised, controlled, external pilot study

### Study type(s)
Treatment

### 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(s)

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

### Key secondary outcome(s)
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex

### 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
United Kingdom

England

### Study participating centre
**St Gemma's Hospice**
Leeds
United Kingdom
LS17 6QD

## Sponsor information

### Organisation
University of Leeds (UK)

### ROR
https://ror.org/024mrxd33

## Funder(s)

### Funder type
Charity

**Funder Name**
Cancer Research UK (UK) (ref: C18324/A7715)

**Alternative Name(s)**
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/04/2010 | | Yes | No |
| Plain English results | | | | No | Yes |