ISRCTN56847801 https://doi.org/10.1186/ISRCTN56847801

# A comparative study of static magnetic field (SMF) therapy against transcutaneous electrical nerve stimulation (TENS) therapy on mechanical back pain and neck pain

**Submission date**
30/09/2004

**Recruitment status**
No longer recruiting

**Registration date**
30/09/2004

**Overall study status**
Completed

**Last Edited**
14/11/2014

**Condition category**
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N0355127318

# Study information

## Scientific Title

## Study objectives
The project aims to identify:
1. The efficacy of magnet therapy for treating chronic mechanical back and neck pain
2. The efficacy of magnet therapy against traditional TENS therapy for treating chronic mechanical back and neck pain

Hypothesis:
Using magnetic therapy will decrease pain and improve quality of life, sleep, reduce analgesic intake more than traditional TENS therapy on mechanical back and neck pain.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied
Musculoskeletal Diseases: Back pain

## Interventions
Patients referred via the three chronic pain consultants will be entered into the study if fitting the inclusion criteria.
A trial of two therapies: conventional TENS using a programmable machine and a specific programme for 2 hours three times a day or a magnetic belt which will work continuously between rising and bedtime. They will be randomly selected for a trial of a TENS machine or magnetic belt for a period of 6 weeks. There will be a week's window before the cross-over therapy for a further 6 weeks. At each completion of the therapy a short evaluation questionnaire will be completed. Normal analgesics can be continued throughout the trial but

they are advised that if they receive benefit from the therapy they can reduce their analgesic intake.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
We have developed a short questionnaire to be completed at the end of each therapy to identify if there has been any change in the pain or their behaviour. We are looking for differences in:
1. Level of pain
2. Functional activity
3. Medication reduction
4. Sleep activity
5. Quality of life
Each section can score a maximum of 20, the lowest number of 0 being the best outcome. The total of all sections are calculated to a maximum of 100. The higher the score the worse the outcome.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/08/2003

### Completion date
30/04/2004

## Eligibility

### Key inclusion criteria
1. Chronic pain consultants referrals only
2. Patients normally eligible for TENS therapy
3. Ability to understand simple instructions
4. Ability to apply therapies by self/significant other
5. Patients with a diagnosis of mechanical back or neck pain only (no neurological deficits)

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
25 for TENS and 25 for magnet therapy

### Key exclusion criteria
1. Patients who have a pacemaker
2. Have intracranial clips/aneurysms
3. Would not be able to apply therapies by self or have no help for applying
5. Are outside the age range
6. Are pregnant or may be trying to get pregnant

Reasons include: magnets can increase the failure of pacemakers, having metal work within the head area. Pregnancy: magnets may be harmful to the unborn child (although it has not been clinically proven).

### Date of first enrolment
01/08/2003

### Date of final enrolment
30/04/2004

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Mid Essex Hospital Services NHS Trust**
Chelmsford
United Kingdom
CM1 7ET

## Sponsor information

### Organisation
Department of Health

### Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

### Sponsor type
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

**Funder type**
Government

**Funder Name**
Mid Essex Hospital Services NHS 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