

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	☐ Prospectively registered
Registration date 30/09/2004	Overall study status Completed	☐ Protocol
Last Edited 14/11/2014	Condition category Musculoskeletal Diseases	☐ 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

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Mid Essex Hospital Services NHS Trust

Chelmsford

United Kingdom

CM1 7ET

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Mid Essex Hospital Services NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration