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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