ISRCTN32619262 https://doi.org/10.1186/ISRCTN32619262

The effects of transcutaneous electrical nerve stimulation (TENS) on pain and disabilities in the treatment of patients with chronic pain

Submission date 15/09/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/09/2010	**Overall study status** Completed	
Last Edited 20/11/2012	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

The short and long-term effects of transcutaneous electrical nerve stimulation (TENS) on pain and disabilities in the treatment of patients with chronic benign pain: a randomised double-blind placebo (sham TENS) controlled clinical trial

Study objectives
Transcutaneous electrical nerve stimulation (TENS) is an easy to use analgesic intervention for the treatment of pain. However, although TENS treatment exists since the early 1970s, for chronic pain its effects are still inconclusive. Importantly, It is assumed that the analgesic effect of TENS declines in time by repeated application, threatening the use for chronic pain. Furthermore, it is assumed that improvements lasting for more than three months cannot be attributed to placebo effects. However, long-term randomised placebo controlled TENS studies with treatment periods of more than three months, have not been executed.

We therefore explored the short and long-term time courses of the analgesic effects of repeated TENS application compared to sham TENS in patients with chronic pain, for a maximum period of one year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The committee for Research on Human Subjects of Arnhem-Nijmegen (Commissie Mensgebonden Onderzoek Regio Arnhem-Nijmegen), Radboud University Nijmegen Medical Centre approved on the 7th May 1999 (ref: CWOM-nr.: 9906-0116)

Study design
Single centre prospective double blind randomised placebo controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic pain (non-cancer)

Interventions
Patients will be randomised to receive either:
1. Transcutaneous electrical nerve stimulation (TENS): pulse frequency is set to 80 Hz and pulse width to 0.50 ms, intensity: strong tingling, not pricking sensation. Electrode placement at the sites of hyperalgesia.
2. Placebo: Sham-TENS; same device and application, however no current to the electrodes.

Both groups receive daily treatments for a maximum period of one year.

Intervention Type
Other

Phase

Not Applicable

Primary outcome(s)
Proportion of patients satisfied with treatment result and willing to continue treatment. From patients who ceased treatment because they were no longer satisfied with treatment result, the date of cessation of treatment is used for survival analysis.

Key secondary outcome(s))
1. Overall improvement: a percentage change from baseline; nil percent meaning no improvement at all and hundred percent meaning complete recovery.
2. Pain intensity is measured with a 10-centimeter long Visual Analogue Scale (VAS). Descriptors at the beginning and at the end of the scale are 'no pain at all' and 'maximal imaginable pain'. Patients rate their pain at the same time every day for one week.
3. Perceived health status is measured by the sickness impact profile (SIP). The SIP was developed to provide a measure of perceived health status that is sensitive enough to detect changes or differences in heath status that occur over time or between groups. The SIP contains 136 statements about health-related dysfunction in twelve areas of activity (sleep and rest, eating, work, home management, recreation and pastimes, ambulation, mobility, body care and movement, social interaction, alertness behavior, emotional behavior and communication.
4. Disability because of pain is measured with the Dutch version of the Pain Disability Index (PDI). The PDI was developed as a brief, self-report indicator of pain-related disability. It was constructed as a 7-item questionnaire, which is scored on a scale of 0 (no disability) to 10 (total disability). The items ask for the level of limitations in the total range of role functioning: family /home responsibilities, recreation, social activities, occupation, sexual behavior, self-care and life-supporting activities.
5. Duration of TENS use (hours) serves as a measure for compliance. Duration of actual use of the device, is registered during each visit; it can be read out by pressing a special key combination.
6. Placebo credibility is assessed after the initial treatment period (short-term effect) by asking the patients how certain they feel about having a TENS or placebo device, using a questionnaire according to Deyo et al.
7. Co-intervention: Registration of pain medication: The used daily dose/ the defined daily dose ratio is used to calculate the drug load in treatment groups, as published by the World Health Organization (http://www.whocc.no/atcddd/).
8. Adverse effects: Patients are asked to report problems with device or electrodes and are instructed to recognize symptoms of allergy of electrode materials.

Data collection is performed from patients, as long as they are satisfied with treatment result, for a maximum period of one year. At three, six and 12 months after the initial treatment period patients, still satisfied with treatment result, are invited to the outpatient clinic for assessing pain disability, perceived health status and for retrieving data from previous TENS use. Every month, pain diaries are sent by mail to register pain intensity and pain medication use during one week.

Completion date
26/01/2004

Eligibility

Key inclusion criteria

1. Patients with chronic non-cancer pain referred to the Pain Centre
2. Duration of pain greater than 6 months
3. Age above 18 years, male and female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Previous TENS treatment
2. Pain in face or head
3. Several unrelated sites of pain
4. History of a cerebral vascular accident
5. No assistance at home - e.g. relatives or friends - to help replace or connect the electrodes
6. Involvement in ongoing litigation because of their pain
7. Psychological intervention proposed by the Pain Centre psychologists

Date of first enrolment
01/01/2000

Date of final enrolment
26/01/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Radboud University Nijmegen Medical Centre
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6500 HB

Sponsor information

Organisation
The Netherlands Organization for Health Research and Development (ZonMw) (Netherlands)

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organization for Health Research and Development (ZonMw) (Netherlands)
(ref: 940-31-053)

Results and Publications

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?
Results article	results	01/09/2006		Yes	No
Results article	results	01/05/2008		Yes	No
Results article	results	01/09/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes