Is Transcutaneous Electrical Nerve Stimulation (TENS), as proveide in daily care, an effective method to modulate pain transmission in patients suffering from chronic non-specific pain syndromes?

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Is effectiveness of TENS, in reducing pain, in responders based on modulation of pain transmission and perception, as measured by CHEPS? Is the ability of TENS to modulate pain transmission and perception influenced by abnormal pain processing? Are...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON33843

Source
ToetsingOnline

Brief title
TENS in chronic pain; responders and non-responders?

Condition

- Other condition

Synonym
chronic pain, chronic widespread pain

Health condition

patienten met chronische aspecifieke (onduidelijk somatisch substraat) pijn van houdings- en ebwegingsapparaat

Research involving
Human

Sponsors and support

Primary sponsor: Pijnkenniscentrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chronic pain, pain thresholds, pain transmission, TENS

Outcome measures

Primary outcome

Decrease in amplitude of CHEPS in responders vs. non responders

Severity of pain: 100 mm Visual analogue Scale.

Secondary outcome

Changes in thermal, mechanical and pain thresholds.

Study description

Background summary

Transcutaneous electrical nerve stimulation (TENS) is a frequently applied therapy in chronic pain. Although evidence regarding the effectiveness of TENS in chronic pain is inconclusive many patients continue using TENS on long term in daily practice.
An important question is therefore why some patients respond well and others don*t at all.
Due to the heterogeneity of chronic pain patients, where psychosocial factors may influence pain, one cannot expect that all patients will respond equally to TENS. In chronic pain evidence for abnormal pain processing (sensitization) has been found in several patients groups. The process of sensitization might influence effectiveness of TENS as the theoretical working mechanism of TENS is based on the modulation of the transmission of nociceptive impulses form peripheral receptors throughout spinal nerve system into the brain. The

question is whether the effect in the responder group is due to an adequate modulation of pain transmission or do other factors influence the ability to modulate this process?
In this study we want to study the effect of TENS on pain transmission, as measured by contact heat evoked potentials (CHEPS), between *responders* and non-responders* after a two weeks TENS treatment. A subjective pain reduction of >= 30% on a 100 mm Visual Analogue Scale (VAS) is regarded as a clinical relevant score. Therefore *responders* will be defined as patients with a pain reduction of >= 30% on a VAS after a two week treatment period with TENS. Non-responders are patients with a pain reduction < 15%.

Study objective

Is effectiveness of TENS, in reducing pain, in responders based on modulation of pain transmission and perception, as measured by CHEPS? Is the ability of TENS to modulate pain transmission and perception influenced by abnormal pain processing? Are sensory and/or pain thresholds at baseline predictive factors voor effect of TENS, based on responders/ nonrespondersship?

Study design

prospective cohort study

Intervention

Patients receive a two week treatment period with TENS-treatment at home after instruction. The frequency is set at 100 Hz and pulse duration at 250 µ sec. Patients have to use the TENS daily (minimal 4 times a day for 30 minutes).

Study burden and risks

Effectiveness of TENS treatment in chronic pain is still inconclusive. This study provides information about possible subgroups of patients who will have better outcome for TENS. Results of this study can help to identify possible subgroups of patients who will benefit from TENS. Being able to identify patients with favourable outcome, may allow efficient selection, while reducing the cost and disappointment of non-success in general practice. Criteria to select patients at poor or good outcome could also be used in randomised trials. The risk associated with participation in TENS treatment can be considered negligible and the burden minimal. TENS treatment is regarded as a safe and easy to administer intervention.
The measurementsprotocol is without risk en are combined with treatment appointments. De duration of the measurement is about 2.5 houres (each time), which is a normal duration as performed in daily clinical practice. Total duration of maesurements is 5 houres.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

a) referred for TENS treatment by a pain physician,
b) duration of pain > 6 months,
c) age above 18,
d) no current other treatment for pain

Exclusion criteria

The physician at the pain clinic checks criteria based an anamenesis and physical examination:
a) pain due to cancer,
b) the use of a cardiac pacemaker,

c) pregnancy,
d) neurological sensory deficits,
e) language and/or cognitive inability to complete the health assessment questionnaires
f) previous TENS for pain relief.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-04-2009
Enrollment:	62
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	13-05-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT00885859
CCMO	NL26085.068.09