The effect of cervical transcutaneous electrical neurostimulation on cerebral blood flow velocities, a phase 1 study

Published: 15-12-2008 Last updated: 07-05-2024

To find out if cervical TENS affects cerebral bloodflow as measured with transcranial doppler sonography in healthy subjects, and to find a dose-response relation for this effect. To find out if cervical TENS can suppress sympathetic tone as...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31610

Source ToetsingOnline

Brief title Cervical TENS and CBF

Condition

• Central nervous system vascular disorders

Synonym cerebral vasospasm, spasm of the vessels in the brain

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen **Source(s) of monetary or material Support:** Ministerie van OC&W

1 - The effect of cervical transcutaneous electrical neurostimulation on cerebral bl \dots 15-05-2025

Intervention

Keyword: Cerebral bloodflow, Transcutaneous Electrical Neurostimulation

Outcome measures

Primary outcome

Cerebral bloodflow as measured by transcranial doppler sonography.

Secondary outcome

Bloodpressure and pulse.

Registration of adverse events.

Study description

Background summary

Transcutaneous electrical neurostimulation (TENS) has been shown to reduce sympathetic tone. TENS is to be considered the cutaneous analogue of Spinal Cord Stimulation (SCS), which has been proven to improve coronary, cerebral and peripheral blood circulation. In this line of thought TENS might be a useful adjunct in treatment of vasospasm in Subarachnoid Hemorrhage (SAH) patients. Before using TENS in SAH patients, a dose-response relation and safety analysis has to be done.

Study objective

To find out if cervical TENS affects cerebral bloodflow as measured with transcranial doppler sonography in healthy subjects, and to find a dose-response relation for this effect.

To find out if cervical TENS can suppress sympathetic tone as measured with transcranial doppler sonography in healthy hyperventilating subjects.

Study design

Controlled (subject is own control), non-randomized trail. Phase I-II study.

Study burden and risks

The only known risk of TENS is local cutaneous irritation. From clinical

studies with cervical SCS it is known that there are no adverse systemic effects of cervical electrical neurostimulation. Hyperventilation can cause dizziness and peripheral paresthesia. No adverse effects are expected from increased cerebral bloodflow.

There are no benefits for the participating subjects.

Contacts

Public Universitair Medisch Centrum Groningen

Hanzeplein 1 9700 RB Groningen Nederland **Scientific** Universitair Medisch Centrum Groningen

Hanzeplein 1 9700 RB Groningen Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age 25-65 years Informed consent signed by patient

Exclusion criteria

History of vascular disease. History of any neurological disease (including neuropathy). History of cervical or skull-base surgery. Presence of any electronic implant. Use of (para)sympatholytic or (para)sympathicomimetic medication.

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Treatment	

Recruitment

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	30-10-2008
Enrollment:	20
Туре:	Actual

Medical products/devices used

Generic name:	Transcutaneous electrical neurostimulation
Registration:	Yes - CE intended use

Ethics review	
Approved WMO Application type: Review commission:	First submission METC Universitair Medisch Centrum Groningen (Groningen)

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 CCMO **ID** NL19420.042.08