

# The effect of cervical transcutaneous electrical neurostimulation on cerebral blood flow velocities, cerebral vasospasm and ischemic deficit in secondary cerebral vasospasm after subarachnoid haemorrhage

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To find out if patients with secondary cerebral vasospasm after SAH can benefit from cervical TENS.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Central nervous system vascular disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON34128

### Source

ToetsingOnline

### Brief title

Cervical TENS in cerebral vasospasm

### 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

## Intervention

**Keyword:** Cerebral vasospasm, Subarachnoid hemorrhage, Transcutaneous electrical neurostimulation

## Outcome measures

### Primary outcome

Cerebral bloodflow velocities as measured by transcranial doppler sonography

### Secondary outcome

Cerebral ischemia as seen on computed tomography scans

Cerebral oxygenation as measured by near-infrared spectroscopy

Blood pressure and pulse.

Clinical outcome.

## Study description

### Background summary

Transcutaneous electrical neurostimulation (TENS) has shown to reduce sympathetic tone. TENS is to be considered the cutaneous analogue of Spinal Cord Stimulation (SCS), which has 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. We want to perform a prospective longitudinal observational study in patients with secondary cerebral vasospasm after SAH.

### Study objective

To find out if patients with secondary cerebral vasospasm after SAH can benefit from cervical TENS.

### Study design

Pilot with prospective longitudinal observational design.

### **Intervention**

Cervical TENS applied at different frequencies.

### **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. In a previous study we have shown that TENS can be safely applied. Possible benefit could be decrease of cerebral deficits.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

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

## Inclusion criteria

Confirmed aneurysmatic subarachnoid hemorrhage.

Cerebral vasospasm demonstrated by TCD, defined as a MCA/ICA ratio  $>3$

Aneurysm is treated with a surgical or endovascular procedure.

Age  $> 18$  years.

Treatment can be started promptly.

Informed consent signed by patient or family.

## Exclusion criteria

History of cervical spine or skull-base surgery.

Known adverse reaction to TENS-pads.

The presence of any implanted electronic device (including pacemakers).

Pre-existing disease that can obscure follow-up.

Unacceptable interference with cardiographic registration (in case intensive care is necessary).

Insufficient temporal bony windows

## Study design

### Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-09-2010
Enrollment:	10
Type:	Actual

## Medical products/devices used

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

## Ethics review

Approved WMO  
Date: 26-05-2010  
Application type: First submission  
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)  
Approved WMO  
Date: 08-07-2010  
Application type: Amendment  
Review commission: 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	ID
CCMO	NL32001.042.10