The Effects of Transcutaneous Vagus Nerve Stimulation on the Pupil Diameter, Heart Rate and Heart Rate Variability in Epilepsy Patients and Healthy Subjects.

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Primary objective: The main objective of this pilot study is to gain more insight into the effects of tVNS: to assess if the ABVN and consecutively the NTS are really stimulated by tVNS. Therefore this study investigates the effects of tVNS on the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders congenital
Study type	Interventional

Summary

ID

NL-OMON44401

Source
ToetsingOnline

Brief title
Effects of tVNS on the autonomic nervous system

Condition

- Neurological disorders congenital
- Seizures (incl subtypes)

Synonym
Epilepsy

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Het gebeurt in het kader van onderzoek en in het kader van afstuderen. Alles gebeurt in eigen beheer en op de eigen afdeling.

Intervention

Keyword: (t)VNS, Epilepsy, Heart rate (variability), Pupil diameter

Outcome measures

Primary outcome

The primary outcome is the effect of tVNS stimulation on the pupil diameter,

heart rate and heart rate variability.

Secondary outcome

The secondary outcome is the effect of VNS stimulation on the pupil diameter

and heart rate.

Study description

Background summary

Vagus nerve stimulation (VNS) is a form of neurostimulation used for treating patients suffering from refractory epilepsy. Stimulation of the afferent vagal nerve fibers activates the nucleus tractus solitarius (NTS) in the brainstem, which in turn stimulates the locus coeruleus (LC). The projection of the NTS to the LC is suggested to be important for the anti-seizure effect. However, the exact mechanism underlying the effects of VNS are still not fully understood and unfortunately, not all epilepsy patients respond well on VNS. In addition to the anti-seizure effect of VNS, afferent stimulation of the vagus nerve could also affect the autonomic nervous system. The autonomic activities could be a marker for the stimulation effects of VNS.

Recently, a transcutaneous VNS (tVNS) has become available, which could be used as a possible predictor for the effects of an implanted VNS system in epilepsy patients. In order to gain more information about the effectiveness of tVNS, research could be performed on the reflex and sensory responses elicited by tVNS. This might provide functional indicators of the type of fibers recruited

and provide more evidence that tVNS really stimulates the auricular branch of the vagus nerve (ABVN) and can cause an anti-seizure effect.

Study objective

Primary objective: The main objective of this pilot study is to gain more insight into the effects of tVNS: to assess if the ABVN and consecutively the NTS are really stimulated by tVNS. Therefore this study investigates the effects of tVNS on the pupil diameter, heart rate and heart rate variability.

Secondary Objective: To assess the effects of VNS on the pupil diameter and heart rate.

Study design

Prospective single-blind cross-over intervention pilot study

Intervention

The healthy subjects and the 20 patients without a VNS will be measured for approximately one hour with the tVNS. Epilepsy patients with a VNS are measured for approximately 20 minutes with a VNS.

Study burden and risks

Subjects are measured one time. Prior to the measurement a questionnaire is filled in. During the measurement the pupil diameter is measured with an Eye tracker. Cardiac parameters are obtained with the use of an ECG system. There are no specific risks associated with participating in this study. Epilepsy patients are always at risk of having a seizure. Participation in this study is neither increasing nor decreasing the risk. There are also no benefits to be expected.

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

General inclusion criteria:
- Age * 18
- physically and cognitively capable of using the tVNS device and participating in the measurement.
- able to read and understand Dutch. ;For the 40 epilepsy patients there are more inclusion criteria. The 40 patients are subdivided in a patient group with a vagus nerve stimulator and a patient group without a vagus nerve stimulator. ;For the epilepsy patients without a VNS there are more inclusion criteria in addition to the general inclusion criteria:
- diagnosed with epilepsy
- the patients has no implanted VNS system;For the epilepsy patients with a VNS inclusion criteria are also:
- diagnosed with epilepsy
- implanted with a VNS system

Exclusion criteria

- Severe cognitive impairment
- History of cardiovascular disease
- Presence of an eye disease
- Eye surgery in the past
- Implanted with a pacemaker
- Diabetes
- Use of beta blockers

- Use of anticholinergic or psychostimulant medication.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-09-2017
Enrollment:	65
Type:	Actual

Medical products/devices used

Generic name:	Transcutaneous vagus nerve stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-08-2017
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	28-09-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL61731.044.17