Vagus nerve stimulation in epilepsy during physical exercise

Published: 10-04-2012
Last updated: 26-04-2024

- To investigate the cause of the symptoms patients with a vagus nerve stimulator experience during exercise.- To investigate whether there are changes in EEG during stimulation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON37758

Source
ToetsingOnline

Brief title
VNS in epilepsy during physical exercise

Condition

- Cardiac arrhythmias
- Seizures (incl subtypes)
- Upper respiratory tract disorders (excl infections)

Synonym
Vagus nerve stimulation in epilepsy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Epilepsy, Physical exercise, Vagus nerve stimulation (VNS)

Outcome measures

Primary outcome

The main study parameters are lung function parameters, ECG values and blood

pressure and pulse oximetry, during rest and during exercise.

Secondary outcome

Secondary study parameter will be the EEG.

Study description

Background summary

Vagus nerve stimulation is a form of neuromodulation, used as a treatment for refractory epilepsy. Besides the positive effects of this stimulation on the seizure frequency, several side effects are associated with the stimulation, such as coughing, dyspnea and bradycardias. Some patients mention that they do not experience any symptoms during rest, while during exercise they get the idea that they cannot get enough air during stimulation. It remains unclear whether the cause of this is respiratory, laryngeal or cardiac.

Study objective

- To investigate the cause of the symptoms patients with a vagus nerve stimulator experience during exercise.
- To investigate whether there are changes in EEG during stimulation.

Study design

Case control observational study

Study burden and risks

There are no specific risks associated with participating in this study. In epilepsy patients there is the always present risk of a seizure happening. This study is neither increasing nor decreasing this risk. The exercise will not be

maximal; the subjects will exercise at a level they normally do while riding a bike, so no additional risks are expected.

There is no individual benefit for the subjects participating in the study.

Contacts

Public
Medisch Spectrum Twente

Postbus 50000
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NL
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Adults (age > 18 years);
- Diagnosed with epilepsy
- Stable epilepsy
- Mentally competent
- Able to exercise for 20 minutes
(- Implanted with a vagus nerve stimulator)

Exclusion criteria

- Not able to give informed consent
- Known cardiac and/or respiratory diseases

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:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-04-2012
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	10-04-2012
Application type:	First submission
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	NL39555.044.12
Other	www.trialregister.nl; nummer volgt