Vagus nerve stimulation in epilepsy during physical exercise.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22198

Source
NTR

Health condition

Epilepsy
Vagus nerve stimulation
Physical exercise

Epilepsie
Nervus vagus stimulatie
Lichamelijke inspanning

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Medisch Spectrum Twente

Intervention

Outcome measures

Primary outcome

Lung function parameters, ECG values and blood pressure and pulse oximetry, during rest and during exercise.

Secondary outcome

The EEG, during rest and exercise.

Study description

Background summary

Rationale:

Vagus nerve stimulation (VNS) is a form of neuromodulation as a treatment for refractory epilepsy. Besides the positive effect this stimulation can have in patients, many side effects have been reported, including dyspnea, coughing and bradycardias. Several patients also complain that they cannot get enough air when the stimulator is on while exercising.

Objective:

Primary objective: To investigate the cause of the symptoms patients with a vagus nerve stimulator experience during exercise.

Secondary objective: To investigate whether there are changes in EEG during stimulation.

Study design:

This is a case control observational study comparing epilepsy patients with a VNS that experience symptoms during exercise to those who do not experience these symptoms and epilepsy patients without a VNS.

Study population:

For this study, three groups of epilepsy patients will be included (5 patients each). The first group consists of epilepsy patients without a VNS, the second group of patients with a VNS who do not experience symptoms during exercise and the last group consists of patients with a VNS who do experience symptoms during exercise.

Intervention:

The subjects participating in this study will be measured during rest and during a non-maximal ergometry test. During these tests, which will both take approximately 20 minutes, lung function parameters, ECG, EEG, pulse oximetry and blood pressure will be measured. Epilepsy patients with a vagus nerve stimulator will be asked to activate this device to study the effect of this stimulation on the aforementioned parameters.

Main study parameters/endpoints:

The main study parameters are: lung function, ECG, EEG, blood pressure and pulse oximetry.

Study objective

In patients with side effects, during VNS, there is:

1. A decrease in lung function parameters;

2. A reduced increase in heart rate;

3. A reduced increase in blood pressure.

Study design

N/A

Intervention

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Contacts

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Eligibility criteria

Inclusion criteria

1. Adults (age > 18 years);

2. Diagnosed with epilepsy;

3. Stable epilepsy;

4. Mentally competent;

5. Able to exercise for 20 minutes;

6. (Implanted with a vagus nerve stimulator).

Exclusion criteria

1. Not able to give informed consent;

2. Known cardiac and/or respiratory diseases.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2012
Enrollment:	15
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL3219
NTR-old	NTR3371
Other	METC Twente / CCMO : P12-09 / NL39555.044.12;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A