Vagus nerve stimulation in epilepsy during physical exercise.

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22198

Bron
NTR

Aandoening

Epilepsy
Vagus nerve stimulation
Physical exercise

Epilepsie
Nervus vagus stimulatie
Lichamelijke inspanning

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente
Overige ondersteuning: Medisch Spectrum Twente

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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Contactpersonen

Publiek

Medisch Spectrum Twente, Department of Neurosurgery,
P.O. Box 50000
C.C. Vos, de
Enschede 7500 KA
The Netherlands

+31 (0)53 4873532

Wetenschappelijk

Medisch Spectrum Twente, Department of Neurosurgery,
P.O. Box 50000
C.C. Vos, de
Enschede 7500 KA
The Netherlands
+31 (0)53 4873532

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Not able to give informed consent;

2. Known cardiac and/or respiratory diseases.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2012
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3219
NTR-old	NTR3371

Register	ID
Ander register	METC Twente / CCMO : P12-09 / NL39555.044.12;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A