Predicting efficacy of neuromodulation in epilepsy

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23690

Source
Nationaal Trial Register

Brief title
PREDYct

Health condition

Epilepsy

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: • Medisch Spectrum Twente in Enschede
• University of Twente in Enschede

Intervention

Outcome measures

Primary outcome

• The primary goal of the pilot study is to test the feasibility and patients' satisfaction of the subcutaneous electrode.
• If successful, the study will be expanded to a larger cohort. The primary objective of this larger study is to predict success of VNS in patients with epilepsy using pre-operative

features from ultra long-term EEG recordings, resting-state 64-channel EEG and MRI. We will initially aim to predict responders (>50% seizure reduction); this binarized response will be complemented by assessing the likelihood of seizure reduction on a continuous scale.

Secondary outcome

• To evaluate the correspondence between seizures reported by the patients (using diaries) and the seizures recorded by the subcutaneous electrode.
• To study differences in network characteristics derived from 64-channel EEG, and MRI before and after VNS.
• To evaluate the effect of VNS on psychologica) well-being including quality of life, anxiety and depression.
• To evaluate the effect of VNS on sleep quality (total sleep duration, time to first REM, total time in deep sleep measured with the subcutaneous EEG recording).

Study description

Background summary

Rationale: In patients with medically refractory epilepsy who are not eligible for surgical treatment, neuromodulation, including vagus nerve stimulation (VNS), remains as a last resort. However, a good response (> 50% seizure reduction) is achieved in only approximately 50% of patients. At present, we cannot predict who will benefit from VNS. Ultra long-term EEG measurements have recently become feasible by using minimally invasive subcutaneous electrodes. We hypothesize that the combination of this technique with network analysis of resting state fMRI and 64-channel EEG can provide insight in the brain circuits involved in the disturbed brain dynamics and can result in a significant improvement in response prediction of individual patients who are candidates for VNS.

Objective: We aim to identify biomarkers to predict the success of VNS using pre-operative ultra-long EEG recordings, restingstate 64-channel EEG, and MRI.

Main study parameters/endpoints: The primary goal of the pilot study is to test the feasibility and patients' satisfaction of the subcutaneous EEG electrode using a short questionnaire. If successful, the study will be expanded to evaluate the predictive value of the pre-operative ultra long-term EEG recordings measured with the subcutaneous electrode, the pre-operative resting state 64-channel EEG and pre-operative MRI. The primary outcome measure for this prediction model is the response rate (i.e. change in seizure frequency) to VNS assessed with the subcutaneous EEG electrode.

Study objective

We will use ultra long-term EEG measurements that both serve as a reliable and objective measure for electrographic seizures and allow extraction of features that characterize the

epilepsy phenotype as candidate biomarkers to assess the efficacy of neuromodulation. This will be complemented with network analysis of resting state fMRI and 64-channel EEG to provide insight in the brain circuits involved in the disturbed brain dynamics. We hypothesize that this combination of techniques can result in a significant improvement in response prediction of individual patients who are candidates for VNS.

Study design

• EEG will be recorded from 2 months pre-operative until 2 months postoperative, from 5 until 7 months postoperative and from 11 until 13 months postoperative.
• Baseline (2 months pre-operative, before insertion of the subcutaneous EEG electrode) and postoperative (13 months postoperative, after explantation of the subcutaneous EEG electrode) 64-channel EEG and MRI (anatomical, DWI and fMRI).
• Baseline (-2 months) and at the end of the study (+13 months) to fill in four questionnaires about their psychologica) well-being: the Quality of Life in Epilepsy (QOLIE-31-P), the Generalized Anxiety Disorder 7-item (GAD-7), the Patient Health Questionnaire (PHQ-9), and the Beck Depression Inventory-II (BDI-II).
• Three times (-2 months, -1.5 months and +13 months) to fill in a short questionnaire to evaluate the patient satisfaction about the subcutaneous EEG electrode.

Intervention

Not applicable.

Contacts

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Eligibility criteria

Inclusion criteria

• Adult (>=18 year) patients with medically refractory epilepsy, who are candidates for VNS.
• Known with a focal epilepsy with a temporal/frontotemporal seizure-onset zone (as corroborated by EEG or magnetic resonance imaging [MRI]) or a generalized epilepsy.
• A self-reported seizure frequency of at least one seizure per month.

Exclusion criteria

• Prior brain surgery.
• Cognitive impairments that causes the patient to be unable to onderstand the research purpose and give informed consent.
• Exclusion criteria (for safety issues) to ondergo an MRI scan.
• Planned or expected MRI scan during the period where the subcutaneous electrode is implanted.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-07-2020
Enrollment:	5
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description

N/A

Ethics review

Positive opinion

Date:	27-07-2020
Application type:	First submission

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	NL8801
Other	MEC-U Nieuwegein : R20.017

Study results

Summary results

N/A