Predicting efficacy of neuromodulation in epilepsy

Gepubliceerd: 27-07-2020 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23690

Bron
Nationaal Trial Register

Verkorte titel
PREDYct

Aandoening

Epilepsy

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente
Overige ondersteuning: • Medisch Spectrum Twente in Enschede
• University of Twente in Enschede

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

• 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.

Onderzoeksproduct en/of interventie

Not applicable.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	27-07-2020
Aantal proefpersonen:	5
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting

N/A

Ethische beoordeling

Positief advies

Datum:	27-07-2020
Soort:	Eerste indiening

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	NL8801
Ander register	MEC-U Nieuwegein : R20.017

Resultaten

Samenvatting resultaten
N/A