Cerebellar stimulation to treat refractory epilepsy in children

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22556

Bron
Nationaal Trial Register

Verkorte titel
CARE

Aandoening

Refractory epilepsy

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Supported by Boston Scientific

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To determine the efficacy of cerebellar stimulation in children with refractory epilepsy by measuring number and severity of seizures.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:
Epilepsy affects 50 million people worldwide and about 30-40% of these patients will not be adequately controlled with antiepileptic
drugs (AEDs) 1. Meta-analysis of available data suggest that modern AEDs will benefit only about 6% of these patients over
placebo 2. Once established, overall prognosis can be very poor; In Lennox Gastaut syndrome (LGS) for example 90% of patients
are mentally retarded and > 80 % have recurring seizures throughout their adult life 3,4. When surgical intervention is not indicated,
possible or where surgery did not provide relief, deep brain stimulation is an emerging alternative treatment for refractory epilepsy.
New evidence indicates cerebellum might be a potential target to further improve treatment possibilities in these patients. It is our
hypothesis that stimulation of a specific cerebellar area, i.e. cerebellar nuclei (CN), will significantly reduce the number of epileptic
seizures and thereby improve cognitive development and functioning of refractory epilepsy patients.

Objective of the study:
- Decrease epilepsy
- Improve cognition

Study design:
- 3 months baseline registration of epilepsy and cognition
- Surgery with implantation of electrical cerebellar leads, followed by a post-surgical hospitalisation
- 4 weeks after surgery start electrical stimulation
- 6 months after start stimulation first endpoint measurement of epilepsy and assesment of cognition
- 12 months after start stimulation second endpoint measurement of epilepsy and cognition

Study population:
- Children between 4 and 18 years of age with refractory epilepsy

Intervention:
- Electrical stimulation via implanted leads

Primary study parameters/outcome of the study:
- Amount and severity of epilepsy

Secundary study parameters/outcome of the study:
- Cognition corrected for age combined with assesment of behavior, development, daily life

functioning and attention
- EEG parameters
- Adverse events

Doel van het onderzoek

Based on recent data derived from animal research in combination with earlier clinical trials, we hypothesize that stimulation of cerebellar nuclei in pediatric refractory epilepsy patients might be effective in significantly decreasing epileptic seizure frequency, and thereby possibly improving or at least reducing cognitive decline.

Onderzoeksopzet

Baseline visit, Surgery, Start stimulation, Stimulation follow-up visitis (weekly, biweekly, monthly), 6 months follow-up visit, 12 month follow-up visit

Onderzoeksproduct en/of interventie

Electrical stimulation of the brain via implanted leads

Contactpersonen

Publiek

Erasmus MC
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

• Refractory epilepsy for at least one year, with a seizure frequency of at least four per month.
• Failure of at least three adequately tried AED regimens, as determined by the principal investigator, including ketogenic diet if appropriate.
• Age 4 – 18 years at time of inclusion. The first 3 patients are at least 7 years old.
• Definite diagnosis of epilepsy syndrome as reported by treating clinician according to international standards and confirmed by recruitment team.
• Written informed consent of parents/caretakers.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Other progressive neurologic or medical diseases.
• Evident co-existing non-epileptic seizures.
• Candidate for resective epilepsy surgery.
• Inability to complete neuropsychological tests or complete seizure diaries by caretakers.
• Vagal nerve stimulators in situ.
• Surgical contraindications such as coagulation disorders.
• Contraindications for MRI.
• Anatomical abnormalities of skull and posterior fossa, precluding safe lead placement and fixation.
• Immune deficiency.
• Insufficient space or subcutaneous fat to safely implant stimulator.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
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:	01-10-2018
Aantal proefpersonen:	9
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	30-10-2019
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	NL8125
Ander register	METC Erasmus MC : MEC-2016-551

Resultaten