Cerebellar stimulation to treat refractory epilepsy in children

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22556

Source
Nationaal Trial Register

Brief title
CARE

Health condition

Refractory epilepsy

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Supported by Boston Scientific

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

To determine safety and long term effects of (intermittent-) continuous cerebellar stimulation by monitoring number of adverse events, cognitive development, and effects on daily life and behavior.

Study description

Background summary

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

Study objective

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.

Study design

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

Intervention

Electrical stimulation of the brain via implanted leads

Contacts

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Eligibility criteria

Inclusion criteria

• 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.

Exclusion criteria

• 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.

Study design

Design

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

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-10-2018
Enrollment:	9
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	30-10-2019
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	NL8125
Other	METC Erasmus MC : MEC-2016-551

Study results