Cerebellar stimulation to treat refractory epilepsy in children

Published: 21-02-2017
Last updated: 15-04-2024

- Decrease epilepsy- Improve cognition

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Seizures (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON55396

Source
ToetsingOnline

Brief title
CARE

Condition

- Seizures (incl subtypes)

Synonym
refractory epilepsy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Boston Scientific Cooperation International,Matierele en immateriele financiele ondersteuning door Boston Scientific

Intervention

Keyword: cerebellum, epilepsy, refractory, treat

Outcome measures

Primary outcome

- Amount and severity of epilepsy

Secondary outcome

- Cognition corrected for age combined with assesment of behavior, development,

daily life functioning and attention

- EEG parameters

- adverse events

Study description

Background summary

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.

Study objective

- 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

Intervention

- Electrical stimulation via implanted leads

Study burden and risks

This study is a heavy burden on the patient population. In brief, participants are hospitalized pre and post-surgery and are implanted with CS electrodes coupled to a neuro-stimulation device for which post-operative monitoring is required. Participants, or their parents, are furthermore required to keep track of the epilepsy in terms of frequency and severity in a seizure diary.
Pre surgery all participants undergo MRI scanning, 24 hrs EEG monitoring and IQ and cognitive functioning tests. Post-surgery participants receive MRI scanning and in different stages EEG monitoring and cognitive functioning tests.
Since the surgery will be a major component of the burden we briefly explain the procedure:
- Neurosurgical procedure under general anaesthesia for placement of CS electrodes in CDN using standard stereotactic and neuro-navigation techniques, implantation of the neurostimulator device (like a pacemaker) subcutaneously under the clavicular bone and subcutaneously connecting the neurostimulator with the stimulator by electrical wiring. This entire procedure will last approximately 5 - 6 hours.
- Hospitalization after the surgical procedure during 3 to 5 days with post-operative (under general anesthesia) MRI scanning. This post-operative MRI scanning is essential and crucial to determine if the CS electrode is correctly positioned.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

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, including ketogenic diet if
appropriate.
* Age 4 - 18 years at time of inclusion (first 3 patients 7 - 18 years old)

Exclusion criteria

* Other progressive neurologic or medical diseases, including lesions on radioimaging
* Evident co-existing non-epileptic seizures
* Candidate for epilepsy surgery

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-11-2018
Enrollment:	9
Type:	Actual

Medical products/devices used

Generic name:	leads for electrical stimulation
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	21-02-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-01-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-10-2019

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-12-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-05-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL58383.078.16