Effect of surgical treatment on the sleep quality in people with epilepsy

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Sleep disturbances (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON41884

Source
ToetsingOnline

Brief title
Effect of surgery on sleepquality in people with epilepsy

Condition

- Sleep disturbances (incl subtypes)

Synonym
sleep disturbance

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Epilepsie Instellingen Nederland
Source(s) of monetary or material Support: eigen middelen

Intervention

Keyword: DBS, epilepsy, sleep, surgery, VNS

Outcome measures

Primary outcome

Differences in polysomnography (PSG) / EEG parameters before and after surgery

(sleep latency, sleep efficiency, wake after sleep onset, sleep architecture

(distribution of all sleep stages))

Secondary outcome

Differences in scores sleep scales (Groninger Sleep Quality) before and after

surgery

Differences in scores on quality of life scales QOLie-31-P(v2), before and

after surgery

Differences in scores on neuropsychological measures of memory (WMS-R), before

and after surgery

Study description

Background summary

Earlier studies have shown that people with epilepsy report sleep disturbances more often than people without epilepsy. There has been a lot of research regarding the effect of epilepsy surgery on the seizure frequency and quality of life. Research regarding the objective or subjective changes in sleep structure after resective surgery or implantation of a VNS has been scarce. By comparing pre-operative night sleep PSG/EEGs with post-operative night sleep PSG/EEGs, more knowledge will be gathered on the effect of (total) seizure reduction on the sleep in people with or cured from epilepsy. Additionally, a positive effect on quality of sleep and quality of life can be expected after seizure reduction or seizure freedom.

Study objective

The primary objective of this study is to evaluate the effect op epilepsy surgery of implantation of a Vagus Nervus Stimulator on the subjective and objective measures of sleep quality. Secondly the differences in sleep quality and sleep architecture pre and post surgery will be compared, as well for subjective measures of sleep, quality of life and memory function of (former) epilepsy patients.

Study design

Observational study, with a measurement before and after surgery

Study burden and risks

For subjects in this study there are no risks. The burden is for the subjects the (extra) night sleep recording, to sleep with electodes on head and body (EEG, ECG, Respiratory and movements) in the hospotal (the same as pre-surgical). If the results of this study indicate a sleeping disorder the neurologist of this subject will be informed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

An adult (18 years or older) with intractable epilepsy treated in SEIN Zwolle, who underwent resective surgery or had an Vagus Nerve Stimulator or Deep Brain Stimulator implanted. Before surgery a night sleep PSG/EEG recording is performed. This recording was performed 12 months before surgery at most, recorded a minima of 6 hours of sleep and no nocturnal (secundairy) generalized seizure(s) occured during the night

Exclusion criteria

Using a questionnaire, (which is included in the application, and will be given to prospective participants when asked to participate in this study), we exlude participants who have a(n):
- educational level below special elementary education
- history of alcohol or drug abuse during the 1-year period prior to trial participation (criteria for abuse are implemented from health care clinic Jellinek, specialized in abuse)
- the diagnosis of illnesses that affect sleep, like heart failure, cardiac arrythmias pulmonary disease, or sleeping disorders, existing before the diagnosis of epilepsy was made

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	22-04-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL52147.042.15