Partial sleep deprivation in long-term video-EEG monitoring

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To assess the provoking effect of partial sleep deprivation on paroxysmal neurological events in a EMU setting, in people with possible epileptic seizures.

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

Summary

ID

NL-OMON44367

Source
ToetsingOnline

Brief title
Partial sleep deprivation in LTM

Condition

- Seizures (incl subtypes)

Synonym
Seizures

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Epilepsie Instellingen Nederland
Source(s) of monetary or material Support: Aangezien dit onderzoek geen extra kosten met zich meebrengt;is er geen geldstroom voor financiering op te geven.

Intervention

Keyword: EEG, EMU, PNES, Seizures

Outcome measures

Primary outcome

The difference in number of participants in which a habitual event occurred during the EMU recording between the two study groups.

Secondary outcome

- identification of clinical characteristics that are associated with the probability that sleep deprivation can provoke clinical events (etiology of events, specific type of epilepsy/seizures).

- The difference between the two intervention groups concerning the time to the recording of the first habitual paroxysmal neurological event and the wake/sleep state and time of the day in which the events occurs.

- The difference between the two intervention groups concerning the occurrence of the following adverse events: generalized tonic-clonic seizures, seizure clustering.

Study description

Background summary

One diagnostic goal in long-term video-EEG monitoring at an EMU setting is to determine whether paroxysmal neurological events are of epileptic or non-epileptic origin. In order to answer such a diagnostic question, the recording of an actual event is required. Although (partial) sleep deprivation is very often used in tertiary epilepsy centres aiming to provoke clinical events, it has never been investigated whether this actually increases event frequency in either epileptic seizures or non-epileptic (psychogenic) attacks.

Study objective

To assess the provoking effect of partial sleep deprivation on paroxysmal neurological events in a EMU setting, in people with possible epileptic seizures.

Study design

Randomized, open

Intervention

partial sleep deprivation

Study burden and risks

As partial sleep deprivation is already used in longterm monitoring at the EMU, no additional burden or risks are expected. The only extra burden is a questionnare with 5 questions.

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

People above the age of 18 years with paroxismal neurological events, with a clinical suspicion of (focal) epilepsy.

Exclusion criteria

Mentally disabled people
Most likely diagnosis of idiopathic generalized epilepsy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-04-2018
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	06-04-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL61889.058.17