Reducing antiepileptic medication during a multiple-day video-EEG to investigate the feasibility of epilepsy surgery: what is the best way (safest and most efficious) to reduce antiepileptic drugs?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22478

Source
NTR

Brief title
NeedToStop

Health condition

Epilepsy, epilepsy surgery

Sponsors and support

Primary sponsor: Universtiy Medical Center Utrecht
Source(s) of monetary or material Support: Epilepsiefonds

Intervention

Outcome measures

Primary outcome

Predictors of efficacy: A sufficient number of habitual seizures have been recorded.

Predictors of safety: presence of complications, defined as any of the following: status epilepticus (defined as a seizure lasting ¡Ý 5 minutes), seizure clustering (¡Ý 3 seizures in 4 hours), falls and physical injuries, postictal psychosis, generalized tonic-clonic seizures in patients without prior occurrence of these, cardio-respiratory distress, or acute medical complications requiring intervention

Secondary outcome

- The proportion of patients with AED tapering.

- Baseline differences between patients with and patients without AED tapering

- Efficacy comparison between patients with and patients without AED tapering

- Safety comparison between patients with and patients without AED tapering

- Effects of AED withdrawal and restart of AEDs on seizure frequency and cognitive and emotional functioning in the weeks after LTM

Study description

Background summary

Rationale: In people with refractory epilepsy, long-term video-EEG monitoring (LTM) is a valuable tool to evaluate eligibility for epilepsy surgery. For many patients, anti-epileptic drugs (AEDs) are tapered during LTM, but safety concerns have been raised. AED withdrawal might be related to increased complications among which status epilepticus, whilst efficacy has not been established.

Objective: to study the safety and efficacy of AED withdrawal in LTM.

Study design: prospective observational multi-centre study

Study population: children and adults undergoing LTM in the evaluation for epilepsy surgery.

Main study parameters/endpoints: the efficacy endpoint is reached when a sufficient number of habitual seizures have been recorded. Safety is defined by the presence of complications, with any of the following items: status epilepticus (defined as a seizure lasting ¡Ý 5 minutes), seizure clustering (¡Ý 3 seizures in 4 hours), falls and physical injuries, postictal psychosis, generalized tonic-clonic seizures in patients without prior occurrence of these, cardio-respiratory distress, or acute medical complications requiring intervention.

Study objective

Combining factors will enable prediction of successful long-term video-EEG monitoring and of adverse effects, related to antiepileptic drug withdrawal.

Study design

Baseline, during LTM and four weeks after

Intervention

Not applicable

Contacts

Public
HJ Lamberink
Utrecht
The Netherlands
Scientific
HJ Lamberink
Utrecht
The Netherlands

Eligibility criteria

Inclusion criteria

- Long-term video-EEG monitoring (LTM) is initiated in the evaluation for epilepsy surgery (all ages)

- Informed consent signed. In case of age below 16, both parents sign informed consent. For the ages 12-15 (by Dutch law, may be different per country), the child and both parents sign. If they do not, the patient will not participate.

Exclusion criteria

- intracranial long-term monitoring (subdural grid or depth/stereo-EEG)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-04-2017
Enrollment:	850
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-07-2017
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	NL6445
NTR-old	NTR6623
Other	METC UMC Utrecht : METC 17-157/C

Study results