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?

Gepubliceerd: 20-07-2017 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22478

Bron
NTR

Verkorte titel
NeedToStop

Aandoening

Epilepsy, epilepsy surgery

Ondersteuning

Primaire sponsor: Universtiy Medical Center Utrecht
Overige ondersteuning: Epilepsiefonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Baseline, during LTM and four weeks after

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

HJ Lamberink
Utrecht
The Netherlands

Wetenschappelijk

HJ Lamberink
Utrecht
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	10-04-2017
Aantal proefpersonen:	850
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-07-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6445
NTR-old	NTR6623
Ander register	METC UMC Utrecht : METC 17-157/C

Resultaten