Is post-ictal EEG suppression (PGES) in epilepsy caused by excessive cortical inhibition?
Pilot study

Published: 15-03-2017
Last updated: 15-04-2024

To elucidate the role of cortical inhibition in PGES (pilot).

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

Summary

ID

NL-OMON47409

Source
ToetsingOnline

Brief title
Post-ictal EEG suppression and inhibition

Condition

- Seizures (incl subtypes)

Synonym
Epilepsy, seizures

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Epilepsie Instellingen Nederland
Source(s) of monetary or material Support: Christelijke Vereniging voor de Verpleging van Lijders aan Epilepsie

Intervention

Keyword: Epilepsy, Post-Ictal Generalised EEG suppression (PGES), Sudden Unexpected Death in Epilepsy (SUDEP), Transcranial Magnetic Stimulation (TMS)

Outcome measures

Primary outcome

TMS measures of cortical excitability (Motor threshold, Motor evoked potential

amplitude, cortical silent period, short and long recovery curves).

Secondary outcome

Serum levels of anti-epileptic medication

Study description

Background summary

People suffering from epilepsy are more likely to die suddenly without apparent cause than people without the disease. This is termed SUDEP, sudden unexpected death in epilepsy. In recent years, several features associated with epilepsy and seizures have been linked to SUDEP. Post-ictal generalised EEG suppression activity (PGES) is one of them. This phenomenon is often seen in people with convulsive seizures. The mechanism underlying PGES is not well understood. It has been proposed that it is due to excessive cortical inhibition in reaction to the convulsive seizure. Transcranial magnetic stimulation (TMS) is a promising technique to study inhibitory networks in the peri-ictal state.

Study objective

To elucidate the role of cortical inhibition in PGES (pilot).

Study design

Observational pilot study with additional underpowered comparative analysis with healthy controls

Study burden and risks

TMS is a safe technique that is usually well tolerated. TMS will be done every

morning during 5 days (baseline) and a maximum of 3 times in the post-ictal phase. TMS can elicit seizure in people prone to seizures; the risk has been estimated at 2.8% in people with epilepsy who are tapering anti-epileptic medication (Schrader et al., 2004). While this could be seen as an adverse effect, this is not unfavourable in this pre-surgical setting where patients are admitted especially for seizure recordings.

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

Cases
- Aged 18 years or over
- Frequent convulsive seizures (*1 per 12 months)
- Recurring nocturnal seizures

Controls
- Aged 18 years or over
- No epilepsy

Exclusion criteria

Cases and controls
- Pregnancy
- Use or medication other than anti-epileptic drugs that alter cortical excitability (b-blockers)
- performance IQ <80

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-05-2017
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO

Date:	15-03-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

Approved WMO Date:	18-12-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	12-02-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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	NL59016.058.16