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

Published: 26-11-2013
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To elucidate the role of cortical inhibition in PGES (pilot).

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

Summary

ID

NL-OMON38773

Source
ToetsingOnline

Brief title
Post-ictal EEG suppression and inhibtion

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

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

Public
Stichting Epilepsie Instellingen Nederland

Achterweg 5
Heemstede 2103SW
NL
Scientific
Stichting Epilepsie Instellingen Nederland

Achterweg 5
Heemstede 2103SW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Aged 18 years or over
- Frequent seizures (any type) >1 per week
- Frequent convulsive seizures (>1 per 2 months)
- Recurring nocturnal seizures

Exclusion criteria

- 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

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2014
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-11-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (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	NL45936.058.13