

An explorative prospective observational case-control pilot of EEG registration of cortical spreading depression in patients aged 4 years or older, with an acute migraine attack admitted at the headache outpatient service of Medisch Spectrum Twente

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Primary Objective: To measure cortical spreading depression with full-band EEG during the migraine attack at patients aged 4 years or older. Secondary Objective(s): -To explore (additional) signal analysis techniques for detecting CSDs or infra slow...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Headaches
Study type	Observational non invasive

Summary

ID

NL-OMON43771

Source

ToetsingOnline

Brief title

EEG registration in patients with migraine, a cortical spreading depression

Condition

- Headaches
- Age related factors

Synonym

cortical spreading depression, migraine

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Stichting neurologisch onderzoek Twente

Intervention

Keyword: cortical spreading depression, electro-encephalography, infra slow activity, migraine

Outcome measures

Primary outcome

The primary outcome measure will be the number of persons with spreading depolarisations and/or infra slow activity during the migraine attack, which are not present at the control EEG.

EEG will be analysed partially visually and partially by computer. Pathological EEG results as CSD and ISA will be measured dichotomous as *present* and *absent*, and will be quantified in frequency and amplitude. Mann-Whitney-U test will be used to determine the difference in ISA and CSD presence between the cases and controls.

Secondary outcome

To investigate the secondary objectives, the endpoints described as primary endpoint will be necessary. No extra actions will be performed.

Study description

Background summary

The juvenile head trauma syndrome (JHTS) describes a rare phenomenon seen in children. After a mild traumatic brain injury (mTBI), neurological symptoms of drowsiness, a decreased consciousness, confusion, nausea and vomiting, blindness, hemiparesis, and/or seizures appear. The pathophysiology of JHTS is unknown. It is postulated that children with JHTS are more susceptible for cortical spreading depression, as it is a proposed underlying mechanism for migraine. Infra slow activity (ISA) describes brain activity that occurs in frequencies below 0,1Hz²¹ and may be viewed as part of the natural spectrum of rhythmic changes in neuronal network excitability, and is associated with migraine. Infra slow activity from CSD in patients with migraine is recorded by magnetoencephalography¹⁴. Non- invasive detection of infra slow activity of CSD at patients with a migraine attack by more convenient EEG will be the next step.

Study objective

Primary Objective: To measure cortical spreading depression with full-band EEG during the migraine attack at patients aged 4 years or older. Secondary Objective(s):

- To explore (additional) signal analysis techniques for detecting CSDs or infra slow activity.
- To generate hypotheses about the pathophysiology of JHTS.

Study design

This is an explorative prospective observational case-control pilot.

Study burden and risks

EEG is a routine, everyday investigation. Serious or major adverse events are not expected and the risk of an increase of morbidity or mortality is negligible. Potential detrimental effects are discomfort and local skin defects caused by the EEG electrodes. In case of important skin defects, electrodes will be removed. When EEG is frightening for the subjects, and create discomfort, electrodes will be removed.

When unexpected results occur, indicating an unexpected disorder, a neurologist will be asked in consult. He will consider if this discovery has consequences for the patient. If it is, the treating doctor, parent/legal representative and patient will be informed.

The context in which this study is set up is the juvenile head trauma syndrome. As described in the introduction, van der Veek et al postulated that children with JHTS are more susceptible for cortical spreading depression, as it is a proposed underlying mechanism for migraine. Children have a different

manifestation of migraine attacks compared to adults. The duration of a migraine attack can be shorter in children, with a minimum duration of one hour. Localization of the headache can be bilateral, compared to the unilateral localization in adults. There's more variability in associated symptoms; difficulty in thinking, light headedness and fatigue can be presented. EEG at children could show different results compared to EEG at adults. As described in the introduction, Bowyer et al has recorded infra slow activity from CSD in adult patients with migraine by MEG14. It is not yet known if infra slow activity from CSD is recordable in children too.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

Inclusion criteria

- Age 4 years and older.
- Diagnosis of acute migraine attack with or without aura
- Visiting the headache outpatient service

Exclusion criteria

Known comorbidity, that could interfere with the EEG outcome

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	25-01-2016
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO	
Date:	19-01-2016
Application type:	First submission
Review commission:	METC Twente (Enschede)

Approved WMO	
Date:	29-03-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO	
Date:	16-06-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26573

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL55348.044.15
OMON	NL-OMON26573