Cortical Spreading Depression during the onset of migraine; A neurophysiologic study with Direct Current (DC) EEG in migraine patients

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Objectives- To study presence of (Cortical) Spreading Depression ((C)SD), using direct current (DC) EEG changes in migraine patients during different phases of the migraine attack;- Is there a change in DC-EEG recordings suggestive of (C)SD,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Headaches
Study type	Observational invasive

Summary

ID

NL-OMON41337

Source ToetsingOnline

Brief title DC EEG in migraine

Condition

Headaches

Synonym Migraine; headache

Research involving Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

1 - Cortical Spreading Depression during the onset of migraine; A neurophysiologic ... 4-05-2025

Source(s) of monetary or material Support: NWO

Intervention

Keyword: Aura, DC EEG, Migraine, provocation model

Outcome measures

Primary outcome

Outcome measures

Large unilateral DC-potential shifts indicative of a spreading depression

during the onset and duration of a reported aura phase in MA patients, or

during the initiation of a headache phase in MO patients, comparing data from

the two hemispheres. Analyses will be adjusted for end-tidal pCO2 levels.

Secondary outcome

TMS: Motor threshold and stimulus response curves during the different phases

of migraine headache.

Study description

Background summary

Introduction

Migraine is a public health problem of great impact on both the patient and society in western countries. Cortical Spreading Depression (CSD) is considered to be the neurobiological substrate of migraine aura, although CSD has never been recorded directly in migraine patients. Additionally, there is the contested notion that CSD and possible spreading depression (SD; that may occur outside the cortex) may also be involved in migraine attacks without a *perceived* aura (also called clinically silent aura*). To our knowledge, no studies into direct measurements of spreading depression in migraine using EEG techniques have been performed. This study aims to increase our understanding of the role of (C)SD in relation to the onset of migraine with and without aura.

Study objective

Objectives

- To study presence of (Cortical) Spreading Depression ((C)SD), using direct current (DC) EEG changes in migraine patients during different phases of the migraine attack;

- Is there a change in DC-EEG recordings suggestive of (C)SD, synchronous to migraine aura, preceding the migraine headache, in patients suffering from migraine with aura?

- Is there a change in DC-EEG recordings, suggestive of (C)SD, preceding the migraine headache, in patients suffering from migraine without aura?

- To study cortical excitability with TMS and EEG/EMG before and during the initiated migraine attacks.

Study design

Methods

DC-EEG measurement will be performed in migraine patients with and without aura during at maximum 8 hours prior to/ ending in migraine (aura). Three groups will be included: 1) patients with migraine with aura, who are known to be sensitive to visual triggers evoking a migraine aura and/ or attack (n=5 successfully induced auras); 2) Migraine patients in whom a migraine attack is triggered using the GTN-model (n=15 successfully induced attacks); 3) Migraine patients with spontaneous migraine attacks (living or working in the Leiden region, n=5). In addition, end-tidal pCO2 will be systematically recorded using a standard capnograph. If the condition of the subjects permits, at the beginning of the session and before the triggered (but not spontaneous) migraine attack starts, TMS-EEG/EMG will be done., Eventually, subject*s conditions granted, TMS-EEG/EMG will be repeated during and after the migraine attack.

Study burden and risks

EEG-recordings: none

GTN-infusion: light vertigo and light headache during infusion. Within 6 hours: migraine headache will be triggered in 6/10 patients.

LED-bril offering lightflashes: no risks

Oxygenmask: no risk

TMS: can lead to slight discomfort during the evaluation, and some subjects report local pain on the scalp that is not severe and only lasts while the experiment lasts. In rare cases, syncope has been reported. Very rarely, a seizure may be triggered by TMS. The risk amongst people with epilepsy is 0-3.6%.

Burden: there is no direct healthgain for participating patients. Duration of participation (max 8 hours) is moderate duration. After careful consideration, we think possible side effects/ risks are outweight by the expected gain in pathophysiologic knowledge, with hopefully therapeutical consequences.

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

Inclusion criteria are: i) migraine with/ without aura according to the IHS criteria; ii) baseline attack frequency of 1 to 3 attacks per month; iii) moderate or severe headache during attacks; iv) age>18 years; v) residential or working in the Heemstede region or SEIN.

Exclusion criteria

Exclusion criteria are: i) more than 10 days of headache per month; ii) inability to differentiate between migraine and other forms of headache; iii) suffering from another neurologic or psychiatric disease; iv) structural inabilility to stay supine without major movements (e.g. restless legs syndrome, tremor etc.); v) excessive sweating (may influence conduction between skin and electrodes); vii) use of neurologic or psychiatric medication that

4 - Cortical Spreading Depression during the onset of migraine; A neurophysiologic ... 4-05-2025

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):	13-10-2015
Enrollment:	31
Туре:	Actual

Ethics review

Approved WMO	
Date:	18-07-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO	
Date:	08-10-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO	
Date:	15-07-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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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 CCMO ID NL39409.058.12