Pre-ictal cortical excitability features as an early marker for upcoming migraine attacks.

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To capture changes in cortical excitability, by using VEP-EEG recordings at home, in the pre-ictal phase of a migraine attack to serve as an early marker for upcoming attacks.

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

Summary

ID

NL-OMON57041

Source
ToetsingOnline

Brief title
Migraine@Home

Condition

- Headaches

Synonym
headache disorder, Migraine

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Hersenstichting

Intervention

Keyword: Cortical excitability, EEG, Migraine, Pre-ictal

Outcome measures

Primary outcome

The main study parameter is the EEG harmonic response power to visual chirp stimulation in a frequency band of 22-32 Hz during the pre-ictal phase, compared to the interictal phase.

Secondary outcome

The secondary study parameters are:

- EEG driving, harmonic and overall response power to visual chirp stimulation in

o Low frequency band: 10-18 Hz

o Medium frequency band: 19-26 Hz

o High frequency band: 27-40 Hz

o Overlapping frequency band: 22-32 Hz (only for driving and overall response) during the pre-ictal phase, compared to the interictal phase.

- EEG response power at driving, harmonic and intermodulation frequencies in response to visual multisine stimulation.

- EEG resting state power in the traditional delta (0.5-4 Hz), theta (4-8 Hz), alpha (8-12 Hz), beta (12-30 Hz) and gamma (30-80 Hz) ranges during the pre-ictal phase, compared to the interictal phase.

Study description

Background summary

Migraine attacks are highly unpredictable, thereby having a major impact on the daily life of migraine patients - causing increased anxiety, depression, and feelings of loss of control. Unfortunately, the unpredictability of a migraine attack also complicates studying attack-related neurobehavioral and neurophysiological changes. Hence, traditional headache diaries provide insight into attack patterns and provoking trigger mechanisms but lacks continuous information on what happens in the brain or the opportunity for detecting minimal behavioural alterations preceding an attack.
In previous work by our group we have developed a longitudinal protocol for the registration of brain activity by encephalographic (EEG) recordings in the hospital setting. We often found patients experienced no attacks or delayed attacks, possibly due to feelings of stress arising from hospital visits which might have suppressed an impending migraine attack. However, patients that did experience an attack in the hospital setting presented EEG changes prior to the ictal phase that may have potential to serve as an early warning sign for upcoming attacks in the future (Perenboom et al. 2020)1. As a next step, we wish to further strengthen these findings by bringing our recording protocol to the home environment of the patient. Repetitive EEG recordings at patient*s homes are urgently needed to help identify early warning signs of upcoming migraine attacks.

Study objective

To capture changes in cortical excitability, by using VEP-EEG recordings at home, in the pre-ictal phase of a migraine attack to serve as an early marker for upcoming attacks.

Study design

A longitudinal, non-interventional study of VEP-EEG measurements at patients homes.

Study burden and risks

The risk of complications is negligible. Participants might perceive the repeated home measurements as impractical, however, our experience with other repeated measurement studies in migraine patients shows the feasibility of such a study. In addition, patients will fill out a daily e-diary.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- >=18 years of age
- Fulfil ICHD-3 criteria for episodic migraine
- Must experience active migraine; which is defined for this study as at least 1 attack per month, but preferably at least 2

Exclusion criteria

- Unable or unwilling to use the headache E-dairy on a daily basis;
- Diagnosed with other (chronic) neurological diseases such as Parkinson*s disease, epilepsy etc. that may interfere with the results of this study;
- Chronic migraine as defined by the ICHD-3;
- Severe depression and/or panic disorders and/or schizophrenia and/or psychiatric disorders;
- Inability to differentiate between migraine and other headaches;
- Comorbidity with Cluster Headache or other TACs.
- Insufficient proficiency in the Dutch language to complete the headache

e-diary.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-10-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	27-01-2025
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL85619.058.24