Intracranial pressure variability in migraine;
A prospective study to evaluate changes in intracranial pressure during different migraine attack phases

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

Summary

ID

NL-OMON35939

Source
ToetsingOnline

Brief title
Intracranial pressure variability in migraine;

Condition

- Headaches

Synonym
Headache, migraine

Research involving
Human

Sponsors and support

Primary sponsor: Neurologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Headache, Intracranial Pressure, Migraine

Outcome measures

Primary outcome

ICP measurements

- The instrument to be used in the proposed study measures DPOAEs and CM

continuously. From these measurements, phase

shifts of DPOAEs and CM (expressed in degrees) can be

recorded. These phase shifts are correlated to a certain change in ICP,

expressed in daPa/ cm H2O[37].

Clinical symptoms;

- Scoring of migraine attack phase according to the IHS criteria[3];

- Presence of premonitory symptoms (yawning, irritability, food cravings,

fluid retention, depression, irritation, hyperactivation, hypersensitivity,

dysphasia, anorexia, nausea and vertigo);

- Nature of headache symptoms (severity, character, sidedness, aggravation with

physical activity);

- Presence of migraine associated symptoms (nausea, vomiting, photophobia,

phonophobia);

Secondary outcome

not applicable

Study description

Background summary

Background
Migraine is a common, multifactorial brain disorder characterised by chronic, recurrent, disabling attacks of headache with autonomic features (migraine without aura), and, in one third of patients, transient neurological aura symptoms (migraine with aura). Although the pathophysiology of the migraine and aura are reasonably well understood, the triggering mechanisms for the initiation of migraine attacks and the possible role of changes in intracranial pressure (ICP) in relation to the headache phase are unknown. Clinically, diseases with known ICP changes (e.g. tumor cerebri; post-dural puncture headache) share characteristics with migraine, including headaches, nausea and vomiting. However, the relationship between ICP changes and migraine remains unclear. Recently, a non-invasive method to measure ICP using evoked otoacoustic emissions (EOAEs) has been developed allowing more frequent and multiple measurements without the side effects of an invasive technique. This provides an opportunity to study and establish the full profile of ICP changes over time in migraine, including interictal, prodromal, ictal, and post-ictal phases. Knowledge of the role of ICP changes in migraine may increase our understanding of migraine pathophysiology.

Study objective

Objectives
Our main hypothesis is that ICP shows a dynamic profile over the course of different attack phases in migraine. Therefore, we aim to detect dynamic changes in ICP in relation to different phases of the migraine attack. In concreto, the main objectives are:
- To compare ictal ICP to interictal ICP in migraineurs and correlate this with clinical characteristics;
- To compare ictal ICP reactivity to interictal ICP reactivity in migraineurs and correlate this with clinical characteristics;
- To compare the baseline ICP (reactivity) of migraineurs versus healthy controls
Secondary objectives per part of the study include:
- Part I; To correlate measurements via in situ manometry with non-invasive EOAE-based ICP measurements;
- Part II/III; To compare interictal ICP (reactivity) in migraineurs to baseline ICP (reactivity) in healthy controls;
- Part IV; To correlate measurements via lumbar manometry with non-invasive

EOAE-based ICP measurements in migraine and helathy controls;
- Part V; To correlate measurements via lumbar manometry with non-invasive EOAE-based ICP measurements in patients from the Neurology inpatient/ outpatient clinic, with various indications for lumbar puncture.

Study design

Methods and Design
Non-invasive ICP measurements (via an EOAE-based technique using an earplug in the external auditory meatus, comparable to tympanic temperature measurements without any known hazards) will be performed in different study groups:

Part I * EOAE based ICP measurement will be performed twice in patients who have routine, in situ manometry, for on-site validation of this non-invasive technique.
Part II * In migraine patients (without aura), EOAE based ICP measurements will be performed prospectively during a migraine attack (within 0-3 hours from the onset of the headache preferably prior to taking the anti-migraine therapy) and in the interictal phase (>3 days after attack termination). If possible, measurements will also be performed in the prodromal (between 4-48 hours prior to the acute attack) and the post-ictal phase (2-24 hours post pain relieve). Measurements will be performed in three different body positions (upright; supine; and supine with body position in 20* extension) at patient homes.
Part III * In healthy volunteers * matched to migraineurs in part II - EOAE based ICP measurements will be performed twice in three different body positions.
Part IV * in subjects participating in a biochemical study (CME P07.079), who undergo lumbar puncture and lumbar manometry as part of routine technique, EOAE based ICP measurements will be performed in different body positions.
Part V * in patients visiting the Neurology inpatient clinic and outpatient clinic undergoing normal diagnostic lumbar puncture, EOAE based ICP measurements will be performed in different body positions.

Within-subject comparisons will be performed using appropriate statistics with significance level set at $p<0.05$.

Study burden and risks

As mentioned above, the non-invasive measurements of ICP are comparable to measuring temperature through an ear thermometer, i.e. not painful, restricted in time needed (maximum 5 minutes) and without any known side effects. The only discomforts subjects might report is the lack of tolerance for the noise emitted by the ear probes, or a lack of tolerance for having an earplug placed in the ear canal, although this is unlikely since healthy volunteers in previous pilot studies did not report this experience.

In phase I of the proposed study, measurements are to be performed in patients on Intensive and Medium Care units (ICU/ MCU), who are often unable to give informed consent (i.e. legally incapable or incapable of giving informed consent). We deeply considered the possibility of not including such a pilot group in this study. Considering on one hand the fact that the measurement is of non-invasive nature, of very short-lasting time, without side effects and exposes a very low burden to participants, and considering on the other hand the importance of a validation part in our study that enables us to accurately and reliably assess output from this new technique, we feel patient burden and scientific gain are well-balanced. We feel that this study will help the development and accuracy of non-invasive techniques for ICP measurements, enabling reliable use in clinical practice (in ICU/ MCU patients) in some years.

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; i) age between 18-60 years; ii) provided written informed consent; iii) BMI 18.5-30 kg/m2

Exclusion criteria

Exclusion criteria; i) (history of) severe otological disease possibly influencing measurements (e.g. Morbus Menière; hearing loss); ii) patients with a pacemaker and/or deep brain stimulation.

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):	28-03-2011
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	23-03-2011
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	04-06-2012
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	NL35512.058.11