Functionality of the Migraine Brain; a prospective fMRI study

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Objectives- We want to study time-dependent activation in neuronal networks related to pain, vigilance and autonomic functioning in migraine patients during different migraine phases (including premonitory phase);- We want to correlate these changes...

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

Summary

ID

NL-OMON35187

Source
ToetsingOnline

Brief title
Functionality of the Migraine Brain

Condition

- Headaches

Synonym
headache, Migraine

Research involving
Human

Sponsors and support

Primary sponsor: Neurologie
Source(s) of monetary or material Support: NWO

Intervention

Keyword: attack onset, fMRI, migraine

Outcome measures

Primary outcome

Outcome parameters:

- MR: RSN measurements: Time-dependent changes in neuronal activity as

reflected by the BOLD signal in several functional networks;

Time-dependent changes in regions; (voxel-wise) functional connectivity.

- Cognitive tests: results of global-local task

- Venapuncture: levels of female hormones (LH, FSH, oestrogen)

- Questionnaires: information on presence/ absence of premonitory symptoms and

headache

Secondary outcome

n.a.

Study description

Background summary

Background
Migraine is a common, multifactorial brain disorder characterised by chronic, recurrent, disabling attacks of headache, 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 (activation of the trigeminovascular system (TGVS) is pivotal), the triggering mechanisms for the initiation of migraine attacks are not fully understood. Several central nervous system pathways (cortical and subcortical) seem to be involved, including pain pathway, pathways modulating concentration and/ or vigilance, autonomics regions, and brainstem/

hypothalamic networks.

Hypothesis
We hypothesize that migraine related brain networks show time-dependent alterations in activity preceding the onset of a migraine brain and during the different phases of the migraine attack.

Study objective

Objectives
- We want to study time-dependent activation in neuronal networks related to pain, vigilance and autonomic functioning in migraine patients during different migraine phases (including premonitory phase);
- We want to correlate these changes in neuronal activity to clinical alterations.

Study design

Methods and Design
In this prospective study, 20 migraine patients with menstrually related migraine and 20 matched controls (age, oral anti-conceptives; BMI; timing of menstrual cycle) will undergo a daily 15 minute MR-session to asses functionality of the brain at rest using fMRI (RSN), on approximately 5 consecutive days, including days preceding the migraine attack and the first day of the attack proper. Clinical, neuropshychological and biochemical measurements will be performed on every measurement day.

Study burden and risks

n.a.

Contacts

Public
Selecteer

Albinusdreef 2
2333 ZA Leiden
NL
Scientific
Selecteer

Albinusdreef 2
2333 ZA Leiden

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Migraineurs
Inclusion criteria; i) Female migraine patients, suffering from menstrually related migraine according to IHS criteria; ii) in total, 1-2 attacks of migraine per month; iii) aged between 18-50 years; iv) provided written informed consent; v) preferable, no use of acute anti migraine medication during the study* and vi) a regular menstrual cyclus.;Healthy controls
Inclusion criteria; i) Having a regular menstrual cycle; ii) aged between 18-50 years; iii) provided written informed consent;

Exclusion criteria

Migraineurs
Exclusion criteria: i) other neurological or psychiatric disease; ii) contraindications for being in a MR-scanner; iii) use of medications that may influence brain functioning (antidepressants; sedatives); iv) use of prophylactic antimigaine medication; v) presence of premenstrual syndrome; vi) having undergone procedures that influence regularity of menstrual cyclus, such as ovariectomy and hysterectomy; and vii) use of (oral) contraceptives.;Healthy controls
Exclusion criteria: i) any neurological or psychiatric disease, including primary headache syndrome; ii) headache prior to menstrual flow; iii) contraindications for being in a MR-scanner; iv) use of medications that may influence brain functioning (antidepressants; sedatives); v) symptoms of premenstrual syndrome; vi) having undergone procedures that influence regularity of menstrual cyclus, such as ovariectomy and hysterectomy; vii) using medication that is also prescribed for migraine prophylaxis (ß-blokkers etc.), and viii) use of (oral) contraceptives.

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:	Recruitment stopped
Start date (anticipated):	10-11-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	09-11-2011
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	NL38129.058.11