Chronification Of migraine and Pain Experience

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

Summary

ID

NL-OMON56199

Source
ToetsingOnline

Brief title
COPE study

Condition

- Headaches

Synonym
headache, migraine

Research involving
Human

Sponsors and support

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

Intervention

Keyword: chronification, Migraine, pain modulation, sensitisation

Outcome measures

Primary outcome

Part A and part B

Primary outcome measurements for of the three aspects:

i) relative change in peak VAS score;

ii) QST parameters;

iii) corneal nerve fiber density.

& Headache frequency

Secondary outcome

Part A and B

Secondary outcomes for each of the three aspects:

i) change in area under the curve (VAS*sec) of the test stimulus during the

conditioned stimulus;

ii) no additional outcomes;

iii) corneal nerve fiber length and corneal nerve branch density.

Additional outcome measures:

- Sum scores on depression, anxiety and visual sensitivity questionnaires.

Study description

Background summary

Migraine chronification, the transition from low frequent (episodic) migraine, to high frequent (chronic) migraine, occurs in 2.5% of migraine patients every year. Accordingly, in the Netherlands 50.000 migraine patients convert into a severe chronic form each year. The mechanism of migraine chronification remains uncertain, and the pathophysiological differences between episodic migraine and chronic migraine are to a large extent unknown. As for many chronic pain disorders, enhanced pain facilitation (central sensitization) or lack of pain inhibition are suggested as underlying mechanisms. Therefore, the aim of this study is to explore different aspects of central sensitization and pain inhibition in chronic migraine patients and episodic migraine patients

Study objective

The main objectives of this study are:
A) to evaluate the differences between chronic migraine patients, episodic migraine patients an healthy controls with respect to i) pain inhibition, ii) sensory profile and iii) corneal nerve fiber parameters;
B) to evaluate whether chronic migraine patients alter on these three aspects in response to treatment;

Study design

The study consists of a cross-sectional part (part A) and a longitudinal part (part B).
For part A, patients with chronic migraine without medication overuse and episodic migraine will be included, and have one study session. A study session will consist of i) Conditioned Pain Modulation; ii) Quantitative Sensory Testing and iii) Corneal Confocal Microscopy.
In part B, chronic migraine patients with medication overuse will have a study session containing all three measurements before and after treatment. Treatment is regular care and consists of three months withdrawal of overused medication.

Study burden and risks

For this study, we will not adapt current clinical practice. The time burden for a measurement session is approx. 120 minutes. The investigators of the department of Anesthesiology have ample experience with all described sensory tests and cornea confocal microscopy. As described above, is the estimated risk for the patient minimal.

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

Patients with chronic migraine with medication overuse:
i) age between 18 and 75 years;
ii) able to provide written informed consent;
iii) diagnosed with chronic migraine and medication overuse according to ICHD 3-beta criteria. ,

Patients with chronic migraine without medication overuse:
i) age between 18 and 75 years;
ii) able to provide written informed consent;
iii) diagnosed with chronic migraine according to ICHD 3-beta criteria. ,

Patients with episodic migraine:

i) age between 18 and 75 years;
ii) able to provide written informed consent;
iii) diagnosed with migraine with or without aura according to ICHD 3-beta criteria;

Exclusion criteria

Patients with chronic migraine with medication overuse:
i) Other primary or secondary headache syndromes except tension type headache or medication overuse headache

Patients with chronic migraine without medication overuse:
i) Other primary or secondary headache syndromes except tension type headache

Patients with episodic migraine:
i) Other primary or secondary headache syndromes except tension type headache
(ii) A history of chronic migraine according to IHS 3-β criteria <1 year prior to inclusion;
(iii) A history of medication overuse headache according to IHS 3-β criteria <1 year prior to inclusion.

General exclusion criteria:
(i) Neurological conditions, such as peripheral neuropathy or epilepsy, other than the specific types described in the group specific inclusion criteria;
(ii) Any (chronic) pain condition of moderate to severe intensity, or requiring pain medication, other than the types described in the group specific inclusion criteria;
(iii) Psychiatric disease, such as psychosis, other than mild to moderate depression and anxiety, which in the opinion of the investigators may interfere with the study;
(iv) Other medical disease such as pulmonary renal, liver, cardiac, gastro-intestinal, vascular disease, which in the opinion of the investigators may interfere with the study;
(v) Regular use of non-triptan or non-analgesic acute anti-headache medication (e.g. ergots, high dose opioids (low dosages or sporadic/temporary users are allowed), barbiturates) or high dose benzodiazepines;
(vi) Change in use of TCAs (a.o. amitriptyline high dosages (>40 mg/daily), clomipramine, dosulepin, doxepin, imipramine, nortriptyline, maprotiline), SNRIs (a.o. high dose duloxetine / venlafaxine, trazodone), or calcium channel inhibitors (a.o. pregabalin, gabapentin) in the past three months.
(vii) Current abuse or history of abuse of alcohol, soft drugs or hard drugs, which in the opinion of the investigators may interfere with the study;
(viii) Pregnancy or lactation;
(ix) Enrolment in other studies that may confound the results of this study.

Study design

Design

Study phase:	3
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-07-2018
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	25-07-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	24-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	30-08-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (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

ID: 24226
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60419.058.17
OMON	NL-OMON24226