Chronification Of migraine and Pain Experience

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24226

Source
Nationaal Trial Register

Brief title
COPE

Health condition

Migraine chronic and episodic

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Part A and part B
Primary outcome measurements for of the three aspects:
1. relative change in peak VAS score;
2. QST parameters;

3. corneal nerve fiber density.

Part C
- Headache frequency

Secondary outcome

Part A and B
Secondary outcomes for each of the three aspects:
1. change in area under the curve (VAS*sec) of the test stimulus during the conditioned stimulus;
2. no additional outcomes;
3. corneal nerve fiber length and corneal nerve branch density.

Additional outcome measures:
- Sum scores on depression, anxiety and visual sensitivity questionnaires.

Part C
- migraine frequency

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 aim of this study is to explore different aspects of central sensitization and pain inhibition in chronic migraine patients, episodic migraine patients and healthy controls. We expect to find differences between all these groups.

Study design

T=0 / T = 2-3 months / T = 6 months

Intervention

The study consists of a cross-sectional part (part A) and a longitudinal part (part B and C). For part A, patients with chronic migraine and episodic migraine will be included, and have one study session. A study session will
consist of
1. Conditioned Pain Modulation;
2. Quantitative Sensory Testing and
3. Corneal Confocal Microscopy.
In part B, chronic migraine patients 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.
For part C, episodic and chronic migraine included in part A, will be invited to fill out the questionnaires again. During the entire follow-up period (maximum 6 months) patients will be asked to fill out the headache diary. Baseline measurements will be tested as a predictor of increase c.q. decrease of headache frequency.

Contacts

Public
LUMC
Simone Vries Lentsch

0031715262147
Scientific
LUMC
Simone Vries Lentsch

0031715262147

Eligibility criteria

Inclusion criteria

General inclusion:
- age between 18 and 75 years
- able to provide written informed consent
Chronic migraine: diagnosed with chronic migraine and medication overuse according to IHS 3-β criteria
Episodic migraine:- diagnosed with migraine with or without aura according to IHS 3-β criteria
- 1 or 2 migraine attacks per month, with a cumulative duration of ≤ 6 migraine-days and ≤

10 headache days per month.

Exclusion criteria

General exclusion:
- Neurological conditions, such as peripheral neuropathy or epilepsy, other than the specific types described in the group specific inclusion criteria;
- Any (chronic) pain condition of moderate to severe intensity, or requiring pain medication, other than the types described in the group specific inclusion criteria;
- 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;
- 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;
- Regular use of non-triptan or non-analgesic acute anti-headache medication (e.g. ergots, high dose opioids, barbiturates) or high dose benzodiazepines;
- Change in use of TCAs (a.o. amitriptyline, 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.
- Current abuse of, or history of abuse of alcohol, soft drugs or hard drugs, which in the opinion of the investigators may interfere with the study;
- Use of contact lenses (current, or past for > three months) (Corneal Confocal Microscopy specific)
- Pregnancy or lactation;
- Enrolment in other studies that may confound the results of this study.

Chronic migraine: Headache syndrome other than described above as inclusion criteria.

Episodic migraine:
- Headache syndrome other than described above as inclusion criteria;
- A history of chronic migraine according to IHS 3-β criteria;
- A history of medication overuse headache according to IHS 3-β criteria.

Healthy controls:
- Headache syndrome according to IHS 3-β criteria other than self-reported tension type headache ≤ 4 days/month
- Regular use of pain medication (including acetaminophen and NSAIDs) for any condition.

Study design

Design

Study type:	Observational non invasive

Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-07-2021
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-07-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 56199
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9589
CCMO	NL60419.058.17
OMON	NL-OMON56199

Study results