Chronification Of migraine and Pain Experience

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24226

Bron
Nationaal Trial Register

Verkorte titel
COPE

Aandoening

Migraine chronic and episodic

Ondersteuning

Primaire sponsor: N/A
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 and episodic migraine patients

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-07-2021
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	05-07-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 56199
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten