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Subclinical cerebellar dysfunction in patients with migraine

Submission date	Recruitment status	[ ] Prospectively registered
02/05/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/05/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/09/2021	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr W. Brekelmans

Contact details
Leiden University Medical Centre (LUMC)
P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 526 1730
w.brekelmans@umail.leidenuniv.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL914 (NTR938)

Study information

Scientific Title
Subclinical cerebellar dysfunction in patients with migraine

Study objectives
Migraine patients, compared with healthy volunteers, have more subclinical cerebellar dysfunctions, measured by the eye-blinker.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Observational, parallel group, case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Migraine with aura

Interventions
The difference in the conditioning, between migraineurs and healthy volunteers, is measured by using the eyeblinker. The technique is called the chip-MDMT (Magnetic Distant Measurement Technique). A magnet will be placed on the right eyelid. A sensor will be placed below the right eye. So the length, the power and the time of each blink is measured. The test will consist of eight trials of six minutes. A conditioned response will be generated by using airpuffs and tones.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The conditioning as measured with eyeblink between migraine patients and controls.

Secondary outcome measures
1. The sensitivity of the trigeminus system by migraine patients compared with controls: do the results of the disturbed conditioned corresponds to a coordination disorder measured by the sway-test?
2. The relations between the controls, the migraine patients and the patients with a degenerative disease

Overall study start date
01/03/2007

Completion date
10/06/2007

Eligibility

Key inclusion criteria
1. Patients with migraine and aura with minimal six attacks a year (two with aura)
2. Healthy volunteers without migraine
3. Patients with a cerebellar degenerative disease

Participant type(s)
Healthy volunteer

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
For the migraine patients and healthy controls:
1. Neurological diseases in which the function of cerebellum is disturbed
2. The use of medicines/drugs which have influence on the coordination 24 hours before taking part of this examination

Date of first enrolment
01/03/2007

Date of final enrolment
10/06/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre (LUMC)
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (The Netherlands)

Sponsor details
Department of Neurology
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type
Hospital/treatment centre

Website
http://www.lumc.nl/

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leiden University Medical Centre (LUMC) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration