Subclinical cerebellar dysfunction in patients with migraine

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Measuring difference in the conditioning between migraineurs and healthy volunteers, by using the eyeblinker.

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

Summary

ID

NL-OMON31417

Source
ToetsingOnline

Brief title
Subclinical cerebellar dysfunction in patients with migraine

Condition

- Headaches

Synonym
headache

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cerebellum, eyeblink, migraine, Sway-test

Outcome measures

Primary outcome

The eye-blink difference between migrainepatients and controls.

Parameters: CR/UR amplitude, CR/UR onset, CR/UR Peakamplitude and the CR/UR

Peaktime gebruikt (CS= conditioned respons US= unconditioned respons)

Secondary outcome

The sensitivity of trigeminus system by migrainepatients compared with controls.

Do the results of the disturbed conditioned corresponds to a

coordinationdisorder measured by the sway-test?

The relations between the contols, the migrainepatients and the patients with a

degenerative disease.

Study description

Background summary

Earlier examinations possibly shows small damages of the cerebellum in patients with migraine, especially in patients with aura. These defects are structural as well as functional. It is also shown that conditioning largely takes place in the cerebellum. The eye-blinker is a valid method to measure conditioning. The Sway-test is a good methode to measure the coordination and to detect minimal movements.

Study objective

Measuring difference in the conditioning between migraineurs and healthy volunteers, by using the eyeblinker.

Study design

a cross section examination
Controls versus migrainepatiënts with aura

Study burden and risks

The volunteers are asked to come to the LUMC. First the volunteers will be asked to give answers on simple questions about their health, use of medicines and their vision. This will take 5 minutes. The test will consist of 8 trials of 6 minutes. A conditioned respons will be generated by using airpuffs and tones. After 8 trials the coordination will be tested by a sway-test. The total duration of the tests will be less then 90 minutes.

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 migraine and aura with minimal 6 attacks a year (2 with aura).

Healthy volunteers without migraine.
Patients with a cerebellar degenerative diseases

Exclusion criteria

For the migrainepatients and healthy controls: Neurologic diseases in which the function of cerebellum is disturbed.
The use of medicines/drugs which have influence on the coordination 24 hours before taking part of this examination.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

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	NL16940.058.07