Changes in vasoreactivity in migraine and syncope

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1. Is there a decreased total peripheral resistance in supine patients with VVS after challenging them with nitroglycerine? 2. Is there a decreased total peripheral resistance in migraine after infusion of nitroglycerine? 3. What is the relation...

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

Summary

ID

NL-OMON38651

Source
ToetsingOnline

Brief title
Changes in vasoreactivity in migraine and syncope

Condition

- Headaches

Synonym
migraine, vasovagal syncope

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: migraine, NTG, total peripheral resistance, vasovagal syncope

Outcome measures

Primary outcome

At baseline, and during admission of NTG we will measure MAP, CO, TPR, HR, CO2

and TCD non-invasively .

Secondary outcome

none

Study description

Background summary

Migraine patients appear to have a larger and longer lasting decrease in total peripheral resistance after receiving the vasodilator drug nitroglycerin (NTG), given to induce a migraine attack.
NTG is given routinely to patients with presumed vasovagal syncope to induce syncope, which effect is probably also caused by a decrease in total peripheral resistance.
These disorders occur together more often than chance predicts, and might share part of their pathophysiology. Until now, however, their vasodilator responsivity has never been compared. We hope to obtain new information about the pathophysiology of syncope and migraine, which might help to develop new medication.

Study objective

1. Is there a decreased total peripheral resistance in supine patients with VVS after challenging them with nitroglycerine?
2. Is there a decreased total peripheral resistance in migraine after infusion of nitroglycerine?
3. What is the relation between difference in total peripheral resistance and the time to the next migraine attack?
4. Do these findings explain the association between vasovagal syncope and migraine?
5. Is the decrease in peripheral resistance reflected in an abnormal large

decrease of major leg veins?

Study design

Prospective, experimental study

Study burden and risks

Patients with migraine and syncope will be asked to participate by a neurologist in our out-patient clinic. Healthy volunteers will be recruited through public announcement. All subjects will receive a letter informing them about the study. They will be invited to the out-patient clinic for the study. There, they will first undergo a physical examination, and will then receive a canula in the antecubital vein in the supine position. A Finometer continuous blood pressure device (Finapres, Medical Systems) will be attached to the right middle finger. Subjects will be given NTG 0,5 µg/kg/min intravenously for 20 minutes, conform the 'migraine provocation model' (Iversen HK 2001, Juhasz G 2003). Subjects will be informed about the possibility of having a migraine attack after NTG, and will be instructed to stand up slowly after the experiment to avoid syncope. Headache severity will be scored every hour during the experiment using a visual rating scale, ranging from *0* (no headache) to *10* (most severe headache). Afterwards subjects will be asked to fill in a diary and report attacks of migraine within the next 24 hours. There will be no personal benefit for patients.

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

migraine:
-migraine without aura according to the IHS criteria;
-baseline attack frequency of 1 to 8 attacks per 2 months;
-moderate or severe headache during attacks;
-age between 18 and 55 years.
-female;syncope:
-diagnosis of vasovagal syncope confirmed by a tilt table test
- attack history must include at least 5 episodes of syncope or presyncope attacks
-age between 18 and 55 years
-female;migraine and syncope:
-migraine without aura according to the IHS criteria;
-baseline attack frequency of 1 to 8 attacks per 2 months;
-moderate or severe headache during attacks;
-age between 18 and 55 years.
-female
- diagnosis of vasovagal syncope confirmed by a tilt table test or
- attack history must include at least 5 episodes of syncope or presyncopal attacks ;heathy volunteers:
-age between 18-55 years
-female

Exclusion criteria

migraine:
-more than 10 days of headache per month;
-inability to differentiate between migraine and other forms of headache;
-pregnancy;
-current use of vasoactive medication;
-use of more than 4 units of caffeine per day during the last 14 days; ;syncope:
-inability to differentiate between vasovagal and other forms of Transient Loss of Consciousness

-pregnancy
-current use of vasoactive medication
-age beneath 18 or above 55 years
-use of more than 4 units of caffeine per day during the last 14 days;migraine en syncope:
-more than 10 days of headache per month;
-inability to differentiate between migraine and other forms of headache;
-pregnancy;
-current use of vasoactive medication;
-use of more than 4 units of caffeine per day during the last 14 days;
-inability to differentiate between vasovagal syncope and other forms of Transient Loss of Consciousness
-age beneath 18 or above 55 years;healthy volunteers:
-personal or first-degree-relative history of migraine or other primary headache syndrome, except infrequent episodic tension type headache;
- personal history of VVS or any first degree relatives with vasovagal syncope
-headache on > 2 days per month;
-pregnancy
-current use of vasoactive medication;
-use of more than 4 units of caffeine per day during the last 14 days

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2014
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	09-01-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	13-03-2014
Application type:	Amendment
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	NL44488.058.13