Microvascular and Cardiovascular Status of Females with and without Migraine

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

Summary

ID

NL-OMON51120

Source
ToetsingOnline

Brief title
VASCULAR

Condition

- Headaches
- Vascular disorders NEC

Synonym
Migraine

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: NWO Vici beurs

Intervention

Keyword: Cardiovascular risk, Microvascular status, Migraine, Women

Outcome measures

Primary outcome

- Endothelial function measured as changes in dermal blood flow after Local Thermal Hyperaemia using both the LDPI and LSCI expressed in arbitrary units. The parameters of these LTH measurements will be compared between women with and without migraine under three conditions (control condition, after pretreatment with EMLA and L-NMMA).

- Endothelial function measured as Reactive Hyperaemia Index (RHI) using Peripheral Arterial Tonometry (EndoPAT) expressed in arbitrary units.

Secondary outcome

- Determining the agreemement and reproducibility of two devices which measure blood perfusion: the Laser Speckle Contrast Imager (LSCI) and the Laser Doppler Perfusion Imager (LDPI).

- Blood: hormone levels, lipid profiles, vascular biomarkers, inflammatory parameters and DNA.

Other study parameters:

- Demographics

- Vascular risk factors (hypertension, intoxications, obesity, etc.)

- History of disease

- Medication use (painkillers, triptan, ergotamine, oral contraception, etc.)

- Migraine subtype, attack frequency

Study description

Background summary

Migraine is an important and underestimated female-specific cardiovascular risk factor, which occurs three times more often in women compared to men. The association between migraine and cardiovascular disease has been demonstrated in several large epidemiological studies, although the underlying pathophysiological mechanisms remains poorly understood. However, it is suggested that signs and symptoms of cardiovascular disease in women are related to microvascular ischemia and endothelial dysfunction, more so than in men. To date, we have performed non-invasive measurements of the microvasculature in middle-aged women with and without migraine and a history of stroke and polycystic ovary syndrome (PCOS) in order to understand how these diseases interact with migraine to have a synergistic effect on cardiovascular outcome. However, the question remains to what extent these results are generalizable to relatively healthy middle-aged women. Therefore, to gain further insight into the microvascular function of healthy middle-aged women with and without migraine, we will validate our methods by performing non-invasive measurements of the microvasculature in healthy middle-aged (40-60 years) women with and without migraine.

Study objective

The primary objective is to determine and compare the microvascular status between middle-aged women with and without migraine. Secondary objectives include a determination of the agreement and reproducibility of two devices which measure the blood perfusion: the Laser Speckle Contrast Imager (LSCI) and the Laser Doppler Perfusion Imager (LDPI).

Study design

This is a cross-sectional observational study with non-invasive measurements. Also, repeated measurements will take place one month later for half of the participants.

Study burden and risks

Risks of LTH and LDPI/LSCI: none documented. Risks of EndoPAT: none documented. Risks of venipuncture: mild pain and bruising.

The burden for participants will consist of approximately 3 hours per visit.

Half of the participants will be asked to repeat the measurements one month later.

It is possible that mild discomfort will be experienced during inflation of blood pressure cuff lasting for five minutes. Furthermore, a venipuncture will be performed for blood withdrawal which may lead to pain and/or bruising.

Participation does not hold health related benefits for the participants, but participants will be offered a financial compensation.

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

In order to be eligible to participate in this study, a subject must meet all

of the following criteria:

- Women aged 40-60 years without a history of ischemic stroke, preeclampsia and PCOS (i.e. control group, free of comorbidities which have been investigated in our previous multicenter CREW-MIST consortium);
- If the participants are still fertile, they should fulfill at least one of the following criteria:
o a regular menstrual cycle of 25-30 days as measurements will be performed in the middle of their cycle;
o use of oral combination pill and inclusion should not take place in the withdrawal week;
o use of Mirena, Kyleena, Liletta, and Skyla (hormonal intrauterine devices) or Nexplanon/Implanon (etonogestrel birth control implant).
- Capable and willing to provide informed consent.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- A medical history or self-reported symptoms of conditions related to (peripheral) vascular disease, e.g. cardio- or cerebrovascular events, peripheral arterial disease, chronic kidney disease, (pre)diabetes mellitus, uncontrolled chronic hypertension, congestive heart failure, hyperlipidemia, hypercholesterolemia, et cetera;
- Current use of any drugs as primary or secondary prevention of cardiovascular disease;
- Current or former non-incidental smoking (all substances);
- Alcohol consumption of more than seven alcohol units per week;
- Current or prior substance dependence/addiction (alcohol, illicit drugs, tranquillizers, narcotics, analgesics);
- Current pregnancy;
- Insufficient mastery of Dutch or English;
- Any other (serious) illnesses that can compromise study participation;
- Skin conditions (e.g. psoriasis, eczema, rosacea), scars or tattoos on ventral side of lower arm or digits;
- (Any known) allergy for EMLA or L-NMMA;
- Any COVID-19 related symptoms (we will perform a screening by phone) on the day of the measurements.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-09-2021
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	11-05-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL75720.078.20