

Characteristics of female patients with migraine attacks associated with sex hormone fluctuations

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Primary objective: To compare migraine attack duration between menstrually-related migraine attacks and non-menstrually-related migraine attacks. Additional objectives: - To compare clinical characteristics between menstrually-related migraine attacks...

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

Summary

ID

NL-OMON45933

Source

ToetsingOnline

Brief title

The WHAT! - Diary Study

Condition

- Headaches

Synonym

headache, migraine

Research involving

Human

Sponsors and support

Primary sponsor: Neurologie

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Menstrual cycle, Menstruation, Migraine, Sex hormone fluctuations

Outcome measures

Primary outcome

Migraine attack duration

Secondary outcome

Secondary study parameters:

Clinical characteristics of migraine attacks:

- Migraine attack severity
- Migraine associated factors (photophobia, phonophobia, nausea, vomiting)
- Aura symptoms
- Efficacy of acute medication use: type and dosage
- Migraine attack timing during menstrual cycle

Hormone-related characteristics:

- Menstrual cycle length
- Premenstrual complaints based on Daily Record of Severity of Problems

Tertiary study parameters:

Clinical characteristics of migraine patients:

- Migraine attack frequency per month
- Number of migraine days per month

- Number of headache days per month
- Current prophylactic medication use: type and dosage
- Current exogenous sex hormone use: type
- Current climacteric symptoms based on Greene Climacteric Scale
- Current premenstrual syndrome and/or premenstrual dysphoric disorder based on

Daily Record of Severity of Problems

- Current depression and anxiety symptoms based on HADS, CES-D, MASQ-30
- Menstrual cycle history
- Obstetric history

Study description

Background summary

The incidence and prevalence of migraine is three times higher in women than in men. Clinical and epidemiological studies suggest a prominent role for sex hormones in female migraine patients. Menstruation is an important factor increasing the susceptibility for an upcoming attack. Hormonal fluctuations during menopausal transition are also associated with increased susceptibility for migraine. In contrast, pregnancy, lactation and postmenopausal status are associated with an improvement in migraine. Thus, sex hormonal conditions are known to affect the susceptibility for migraine attacks in women, but there is a lack of understanding of the underlying pathophysiological mechanism.

Study objective

Primary objective:

To compare migraine attack duration between menstrually-related migraine attacks and non-menstrually-related migraine attacks.

Additional objectives:

- To compare clinical characteristics between menstrually-related migraine attacks and non-menstrually-related migraine attacks.
- To compare hormone-related characteristics between menstrual cycles in which a menstrually-related migraine attack occurred and menstrual cycles in which a menstrually-related migraine attack did not occur.

- To compare clinical characteristics between patients with current menstrual migraine and current non-menstrual migraine.
- To compare hormone-related characteristics between patients with current menstrual migraine and current non-menstrual migraine.
- To compare depression and anxiety symptoms between patients with current menstrual migraine and current non-menstrual migraine.

See for definitions on clinical characteristics of migraine attacks, hormone-related characteristics and clinical characteristics of migraine patients "secondary study parameters".

Definition of current menstrual migraine: migraine attacks occur on day 1 ± 2 of menstruation in at least 2 out of 3 menstrual cycles based on the prospective diary of 3 menstrual cycles. Includes: pure menstrual migraine without aura, pure menstrual migraine with aura, menstrually-related migraine without aura, menstrually-related migraine with aura.

Definition of current non-menstrual migraine: no migraine attacks occur on day 1 ± 2 of menstruation in at least 2 out of 3 menstrual cycles based on the prospective diary of 3 menstrual cycles. Includes: non-menstrual migraine without aura and non-menstrual migraine with aura.

Study design

We will prospectively study on a daily basis female migraine patients during three subsequent menstrual cycles. Participants will fill out a diary until the onset of the fourth menstruation with a maximum of 105 days. A key feature will be the implementation of modern data recording (web-based smart phone app). This new technology will facilitate the real-time capture of migraine characteristics, greatly improving the sensitivity and accuracy of the information collected. Migraine patients, at least 18 years of age but not postmenopausal and not using continuous sex hormonal therapy, are recruited via the Headache clinic of LUMC and existing research databases, e.g. the Leiden University Medical Centre Migraine Neuro Analysis programme (LUMINA) database (P12.201). After written informed consent is obtained patients will provide input on a daily basis during three subsequent menstrual cycles, with a maximum of 105 days, about the timing of their migraine attacks and the characteristics, e.g. accompanying symptomatology including aura symptoms, duration and severity of attacks, use of acute and prophylactic migraine treatments, menstrual cycle status, premenstrual complaints and exogenous sex hormone use. In addition, participants are asked to fill out two electronic questionnaires on severity of headache symptoms, impact on daily life, depression and anxiety symptoms, menstrual cycle history, climacteric symptoms, obstetric history and history of exogenous sex hormone use. One of these questionnaires only applies to participants who are recruited through the LUMINA database and have not already completed this questionnaire during the last 6 months.

Based on these data obtained from a large number of patients (approximately 500 female migraine patients with a full data set), we will determine which characteristics of female migraine patients are likely to predict the presence of an important role for sex hormone fluctuations in the provocation of migraine attacks.

Study burden and risks

Participation does not hold benefits for the participants. Although some questionnaires might be confronting for patients we strongly believe this is outweighed by the advantages.

The burden of participation will consist of:

- Filling out the electronic LUMINA questionnaire on severity of headache symptoms, impact on daily life, depression and anxiety symptoms (time * 40-50 minutes). This questionnaire only applies to participants who have not already completed this questionnaire during the last 6 months.
- Filling out an electronic questionnaire on menstrual cycle history, history of climacteric symptoms, obstetric history and history of exogenous sex hormone use (time * 30 minutes).
- Filling out an electronic diary during three subsequent menstrual cycles on the occurrence of migraine attacks and characteristics, e.g. accompanying symptomatology including aura symptoms, duration and severity of attacks, use of acute and prophylactic migraine treatments, menstrual cycle status, premenstrual complaints and exogenous sex hormone use (time * 5 minutes per day). Participants will fill out this diary until the onset of the fourth menstruation, with a maximum of 105 days.

Contacts

Public

Selecteer

Albinusdreef 2
Leiden 2333 ZA
NL

Scientific

Selecteer

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Female
- At least 18 years of age
- Migraine without aura, migraine with aura or chronic migraine (according to the International Classification of Headache Disorders ICHD-3b)

Exclusion criteria

- Women who are pregnant or breastfeeding
- Continuous combined oral contraceptive use and not willing to insert pill-free weeks during the study
- Other continuous sex hormonal therapies (e.g. hormone-releasing intrauterine device, progesterone-only pill, Implanon NXT, Depo-Provera)
- Spontaneous postmenopausal status (menstrual bleedings have ceased for 12 consecutive months)
- History of unilateral or bilateral oophorectomy
- History of hysterectomy
- Current gynaecological malignancy

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	18-02-2019
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO	
Date:	07-02-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL67076.058.18

Study results

Actual enrolment: 344