The role of sex hormones in the provocation of migraine attacks in female migraine patients

Published: 12-10-2020
Last updated: 21-12-2024

To compare serum estradiol levels during the late luteal phase between 1) women with menstrually-related or pure menstrual migraine and premenopausal controls and 2) perimenopausal migraine patients and perimenopausal controls. Secondary objectives...

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

Summary

ID

NL-OMON52784

Source
ToetsingOnline

Brief title
WHAT! - Hormone measurements

Condition

- Headaches

Synonym
Migraine

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Hormones, Migraine, Women

Outcome measures

Primary outcome

Serum levels of estradiol during days 8, 10, 12 and 14 after the LH surge

Secondary outcome

Serum levels of progesterone during days 8, 10, 12 and 14 after the LH surge

Serum levels of estradiol and progesterone during days 1, 2 and 3 after the LH surge

Serum levels of 17-hydroxyprogesterone, testosterone, dihydrotestosterone, androstenedione, DHEA, DHEAS, SHBG, LH, FSH and CGRP during days 1, 2, 3, 8, 10, 12 and 14 after the LH surge.

Study description

Background summary

The prevalence of migraine is three times higher in women than 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. Perimenstrual migraine attacks are also more disabling, longer lasting, and more difficult to treat than other attacks. Hormonal fluctuations during menopausal transition are also associated with increased susceptibility for 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

To compare serum estradiol levels during the late luteal phase between 1) women with menstrually-related or pure menstrual migraine and premenopausal controls and 2) perimenopausal migraine patients and perimenopausal controls. Secondary objectives are to compare additional serum sex hormone levels (see parameters

for the exact hormones) during the late follicular phase and the luteal phase.

Study design

Observational study in migraine patients and healthy controls

Study burden and risks

Risks related to venapuncture (pain / hematoma). A total of 560ml blood will be collected throughout two subsequent menstrual cycles. This does not pose any health risks. When donating blood a volume of 500ml is collected at once.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Women aged >= 18 years
- Menstrual migraine OR Early menopausal transition phase
- Migraine frequency: >= 1 attack/month
- Regular menstrual cycle with a cycle length between 25-32 days OR LH surge between days 5 and 25 of the menstrual cycle
- Normal, mildly increased or decreased BMI

Exclusion criteria

- Insufficient mastery of Dutch
- Inability to complete the electronic diary in an accurate manner
- Smoking
- Chronic migraine
- Medication-overuse headache (ICHD-3 criteria)
- Women who are breastfeeding, pregnant, or planning to become pregnant
- Oral contraceptive use during the last month and not willing to undergo washout period (stop for one month)
- Other sex hormone containing treatment use during the last month
- Use of corticosteroids during the last month
- Anamnestic signs of anemia
- Any serious illness that can compromise study participation
- Freezer of insufficient quality

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL
Recruitment status: Completed

Start date (anticipated):	28-09-2021
Enrollment:	132
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	12-10-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-05-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	28-11-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	29-12-2023
Application type:	Amendment
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	NL74161.058.20