MoodCycles in women with ADHD

Published: 06-09-2019
Last updated: 10-04-2024

(1) To investigate the relationship between estradiol level and ADHD and mood symptoms within the menstrual cycle in women with ADHD. (2) To investigate if this relationship is comparable between women with and without ADHD.

Ethical review	Not approved
Status	Will not start
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational invasive

Summary

ID

NL-OMON48515

Source
ToetsingOnline

Brief title
MoodCycles in ADHD

Condition

- Cognitive and attention disorders and disturbances

Synonym
AD(H)D, attention disorder with or without hyperactivity

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia Bavo Groep (Den Haag)
Source(s) of monetary or material Support: PsyQ

Intervention

Keyword: ADHD in women, Female hormones, Menstrual cycle, Mood

Outcome measures

Primary outcome

The intra-individual diferences between the three time points (at low, intermediate and high estradiol niveau) on the ADHD-RS within the ADHD group. Covariates and/or confounders are the objective sleep-wake rhythm, subjective fatigue, background variables such as age, educational leven, comorbid psychiatric disorders (incl. PMDD),smoking status, use of medication, and progesterone, LH, FSH, DHEA-S levels.

Secondary outcome

The three time points (at low, intermediate and high estradiol niveau), subjective ADHD-RS scores, objective QbTest scores, subjective QIDS scores of the women with and without ADHD. Covariates and/or confounders are the objective sleep-wake rhythm, subjective fatigue, background variables such as age, educational leven, comorbid psychiatric disorders (incl. PMDD),smoking status, use of medication, and progesterone, LH, FSH, DHEA-S levels.

Study description

Background summary

Women with ADHD have more often and more severe premenstrual mood disorder symptoms (PMDD), compared to women without ADHD, as was shown in our previous research (46% vs. 3-8%). Dopamine and estradiol levels seem to enhance each other. As ADHD is associated with low dopamine neurotransmission, the hypothesis is that ADHD symptoms and mood instability may increase in the low estradiol (premenstrual) phase of the cycle. Regarding the sleep rhythm, in women with PMDD compared to controls, changes in the circadian sleep rhythm have been found, indicating that disturbed sleep may also contribute to the mood symptoms.

Study objective

(1) To investigate the relationship between estradiol level and ADHD and mood symptoms within the menstrual cycle in women with ADHD.
(2) To investigate if this relationship is comparable between women with and without ADHD.

Study design

Prospective observational case-control study

Study burden and risks

The burden for the participants consists of monitoring the severity of mood and ADHD symptoms during two consecutive menstrual cycle months (time investment about 1 hour in total), and the study measurements in the third month: 3x vena puncture for the measurement of hormone levels in blood, one month of wrist Actigraphy (instruction time 30 minutes), 3x objective QbTest assessments (time investment 2 hours), 3x filling out questionnaires (ADHD-RS, QIDS, and a sleep questionnaire; time investment 1,5 hours in total). Total time investment: 6 hours, plus travel time.

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

ADHD and controls:
- Female gender
- Age 18-45 years old
- regular menstrual cycle
- able to fill out Dutch questionnaires
For ADHD group: ADHD diagnosis

Exclusion criteria

- use of hormones
- use of ADHD medication
- use of sleep medication
- alcohol or drug abuse disorder
- a psychiatric disorder that needs immediate treatment
- any somatic disease affecting sleep or the menstrual cycle (e.g. diabetes)
For control group:
- positive screen for ADHD

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:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Not approved

Date:	06-09-2019
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	NL70774.058.19