Hormonal (dys)function in cluster headache

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To compare free testosterone levels between male CCH patients and healthy controls Secondary Objectives: To compare differences in androstenedione, DHEA, DHT and 11oxC19 level, testosterone/estrogen ratio, activin level, inhibin level and morning...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON51927

Source
ToetsingOnline

Brief title
Hormonal (dys)function in cluster headache

Condition

- Hypothalamus and pituitary gland disorders
- Headaches

Synonym
Cluster headache, Hortons Neuralgia

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Innovatiefonds zorgverzekeraars;herstenstichting en Beat the Beast

Intervention

Keyword: Cluster headache, Estrogen, Melatonin, Testosterone

Outcome measures

Primary outcome

Difference in free testosterone between CCH patients versus healthy controls

Secondary outcome

Differences between androstenedione, DHEA, DHT and 11oxC19 steroids levels,

testosterone/estrogen ratio, activin level*, inhibin** level and morning

cortisol level in blood and 6-sulfatoxymelatonin level in nocturnal urine

between:

- All cluster headache groups (ECH patients in bout, ECH patients out of bout

and CCH patients)

- All ECH patients (in an episode and outside an episode) versus healthy

controls

*Inhibin and 11OXC19 levels will be measured only if a difference in

testosterone is observed between groups.

**Activin levels will not be measured if no difference in testosterone and LH

is observed between groups.

Study description

Background summary

Cluster headache is a very severe primary headache disorder for which the cause remains unknown. Interestingly, cluster headache attacks often appear at night,

one hour after falling asleep, suggesting a link with sleep and the biological clock, residing in the suprachiasmatic nucleus of the hypothalamus. Melatonin is produced in the suprachiasmatic nucleus and is closely related to the sleep-wake cycle and the circadian rhythm. Previous studies indicate a lower melatonin production in cluster headache patients. Cluster headache was always considered a *male* disease, although male:female ratio appears to be declining, most likely due to better diagnosis amongst woman. Despite this declining ratio, males are still heavily overrepresented in cluster headache with an estimated male:female ratio of 2:1. Surprisingly, several small scale studies reported lower testosterone levels in male cluster headache patients.

We hypothesize that hormone levels in chronic cluster headache patients will be the most severe affected compared to episodic cluster headache patients and healthy controls.

Study objective

To compare free testosterone levels between male CCH patients and healthy controls

Secondary Objectives:
To compare differences in androstenedione, DHEA, DHT and 11oxC19 level, testosterone/estrogen ratio, activin level, inhibin level and morning cortisol level in blood and 6-sulfatoxymelatonin level in nocturnal urine between:
- All cluster headache groups (ECH patients in bout, ECH patients out of bout and CCH patients)
- All ECH patients (in an episode and outside an episode) versus healthy controls

Study design

Cross-sectional with a longitudinal aspect in episodic cluster headache patients.

Study burden and risks

The burden and risks associated with this study are very low. Only one container of blood will be taken through a single vena punction. Episodic cluster headache patients will be tested twice: inside and outside the cluster bout. Furthermore, participants are instructed to collect overnight urine one night.

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

- Male
- Subjects need to be 18 years or older
- Diagnosed with cluster headache (episodic or chronic) or no headache diagnosis

Exclusion criteria

- Subjects are not allowed to use steroid or melatonin suppletion
- Diagnosis of migraine
- Disease effecting hormonal regulation

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-10-2022
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	01-07-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	30-08-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	27-10-2022
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	28-04-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	21-08-2024
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	NL74876.058.20