Disruptions of the day-night rhythm after treatment for a non-functioning pituitary adenoma; a cross-sectional study using actigraphy.

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1. Are there differences between patients and controls in circadian movement rhythmicity and sleep duration?2. Are these objective measures associated with subjective sleep complaints?3. Are these objective measures associated with decreased quality…

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

Summary

ID

NL-OMON39636

Source
ToetsingOnline

Brief title
Actigraphy in NFMA patients

Condition

- Hypothalamus and pituitary gland disorders

Synonym
Non-functioning pituitary adenoma, non-hormone producing adenoma of the pituitary gland

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Veni-beurs (subsidie ZonMw)

Intervention

Keyword: Actigraphy, Day-night rhythmicity, Non-functioning pituitary adenoma

Outcome measures

Primary outcome

Registration of day-night rhythmicity and objective sleep duration using

actigraphy and sleep diaries

Secondary outcome

Quality of life and subjective sleep quality

Study description

Background summary

Patients treated for nonfunctioning pituitary adenoma (NFMA) suffer from subjective and objective sleeping disorders, despite optimal substitution of pituitary hormones. A possible explanation for these disorders could be that the pituitary tumor itself, and/or the effects of the treatment (surgery/radiotherapy), lead to hypothalamic damage and therefore to hypothalamic dysfunction.
In a pilotstudy in the Leiden University Medical Center, a group of 17 patients was studied for different functions as mediated by the hypothalamus (sleep, biorhythm, blood pressure regulation, temperature, heart rate variability). The day-night rhythm of activity was studied using actigraphy (Actiwatch). The study concluded that there were signs of disruption of the circadian rhythmicity. The current study aims to further confirm the disturbances in a larger cohort of NFMA patients, and to study possible factors that influence those disruptions.
Furthermore, in the pilotstudy we found indications of reduced activity early in the morning, possibly related to the deficit of cortisol in cortisol deficient patients. To study this hypothesis, the current study will perform the measurements of actigraphy and heart rate variability also in patients with primary adrenalinsufficiency or adrenalectomy. These patients will serve as a model for hydrocortisondependency in the absence of a pituitary disorder.

Study objective

1. Are there differences between patients and controls in circadian movement rhythmicity and sleep duration?
2. Are these objective measures associated with subjective sleep complaints?
3. Are these objective measures associated with decreased quality of life?
4. Which patients/ treatment characteristics influence the disruptions of circadian rhythmicity?

Study design

Cross-sectional study in which patients with a non-functioning pituitary adenoma, patients with primary adrenal insufficiency and healthy controls wear an Actigraph (light-weight whatch) for one week, and fill in several questionnaires

Study burden and risks

No risk, minimal burden.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Informed consent
Mentally competent
Age 18-70 years
NFMA patients: treated for non-functioning pituitary macroadenoma, adequate substitution of any hormone deficiencies for at least 4 months. Documented adenopituitary deficiencies.
Hypocortisol patients: treatment for primary adrenal gland insufficiency or bilateral adrenalectomy, adequate substitution of cortisol for at least 4 months.

Exclusion criteria

Pregnancy
Diagnosted sleeping disorder
Diseases of the hypothalamus or pituitary gland other that NFMA
Chronic use of sleep medication or sedative medication
Age >70 years

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-04-2013
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	06-12-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	01-05-2013
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	NL42333.058.12