Day-night rhythmicity in patients with a nonfunctioning pituitary macroadenoma; a prospective study

Published: 01-09-2015
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Research question:1. Do patients exhibit disturbances of sleep duration or circadian locomotor rhythmicity before surgery? 2. Do these variables change after surgery?

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

Summary

ID

NL-OMON42817

Source
ToetsingOnline

Brief title
Day-night rhythmicity in NFMA, prospective

Condition

- Hypothalamus and pituitary gland disorders

Synonym
non - hormone secreting benign tumor of the pituitary gland, nonproducing pituitary macroadenoma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: actigraphy, circadian rhythmicity, nonfunctioning pituitary macroadenoma

Outcome measures

Primary outcome

1. Registration of day-night rhythmicity using actigraphy and sleep diaries

2. Questionnaires assessing sleep quality and quality of life

3. Clinical parameters from standard patient care, e.g. laboratory results, MRI

of pituitary region, and visual field assessment

4. Melatonin in saliva

5. Visual Evoked Potentials

Secondary outcome

none

Study description

Background summary

Patients treated for a nonfunctioning pituitary macroadenoma suffer from subjective and objective disturbances of sleep quality and sleep-wake rhythmicity. These disturbances might be attributed to dysfunction of the central biological clock, a structure in the hypothalamus that lays adjacent to the tumor.
It is unknown whether these invalidating and irreversible symptoms are caused by compression of the tumor against the biological clock (in that case, symptoms would be present before the surgery), or by surgical manipulation during the transsphenoidal removal of the adenoma. Knowledge on the moment when complaints arise will aid in formulating strategies to prevent these complaints.

Study objective

Research question:

1. Do patients exhibit disturbances of sleep duration or circadian locomotor rhythmicity before surgery?
2. Do these variables change after surgery?

Study design

In 50 patients with a NFMA, we will measure sleep quality and sleep-wake rhythmicity both before and after surgery.

Study burden and risks

Low burden, no risks.

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

Diagnosed nonfunctioning pituitary macroadenoma, not yet received surgery

Exclusion criteria

age <18 years or > 70 years old
mentally incompentent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	27-09-2015
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	NL53585.058.15