Hypothalamic dysfunction and sleep.

Published: 07-08-2008
Last updated: 11-05-2024

The aim of this study is to classify hyothalamic dysfunction in patients treated for pituitary tumors. The hypothalamic functions will be investigated in different studygroups, these groups each have a different risk on hypothalamic dysfunction.

Ethical review	-
Status	Pending
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32008

Source
ToetsingOnline

Brief title
Hypothalamic dysfunction and sleep.

Condition

- Hypothalamus and pituitary gland disorders

Synonym
pituitary tumors and non-functional pituitary tumors

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: hypothalamus, pituitary, polysomnography, sleepcharacteristics

Outcome measures

Primary outcome

1. Sleep analysis by polysomnography

2. 24 hour bloodpressure and heartbeat.

3. 24 hour temperature regulation

4. 24 hour rhythm of leptine and melatonine

5. fasting lipids and post-prandial lipids.

6. quality of life questionnaires

7. sleep diary and sleepquestionnaires

8. sleepregistration by actigraphy

9. ambulant polysomnography

10.virgilancy test

Secondary outcome

not applicable

Study description

Background summary

Patients treated for pituitary tumors have a higher morbidity and mortality. The explanation for the higher morbidity is often searched for in hypopituitarism, however the morbidity exists despite adequate hormone replacement. An explanation could be that the pituitary tumors or the effects of treatment of these tumors (surgery/radiation) leads to hypothalamic damage with as a consequence hypothalamic dysfunction.

Study objective

The aim of this study is to classify hyothalamic dysfunction in patients treated for pituitary tumors. The hypothalamic functions will be investigated

in different studygroups, these groups each have a different risk on hypothalamic dysfunction.

Study design

This study has a cross-sectional design and studies the patients discribed in the next text box.

Study burden and risks

non of the measurements have any risks.

Contacts

Public
Leids Universitair Medisch Centrum

albinusdreef 2
2333 ZA Leiden
Nederland
Scientific
Leids Universitair Medisch Centrum

albinusdreef 2
2333 ZA Leiden
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

informed consent
tendency to judge
in patients treated for a non-functioning pituitary adenoma:
-representative ITT
-six months of adequate substitution of pituitary hormones

Exclusion criteria

pregnancy
diagnosed sleepdisorder

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	45
Type:	Anticipated

Ethics review

Approved WMO

Date:	25-08-2009
Application type:	Amendment

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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	NL20195.058.07