head and neck paragangliomas and sleep related complaints

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neoplastic and ectopic endocrinopathies
Study type	Observational non invasive

Summary

ID

NL-OMON32807

Source
ToetsingOnline

Brief title
paragangliomas and sleep

Condition

- Neoplastic and ectopic endocrinopathies

Synonym
carotid body tumor/ glomus tumor

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: carotid body resection, paragangliomas, sleep, sleep apneu

Outcome measures

Primary outcome

results of the sleepregistration with polysomnografy

results of the sleep questionnaires

results of the sleepregistration at home

results of the resting energy expenditure

24 hour meassurements of the blood pressure and pulse

results op the quality of life questionnaires

chemoreflex meassurements

lungfunction

examination of the blood

Secondary outcome

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Study description

Background summary

Patients with head and neck paragangliomas have substantial sleep related complaints. the existence of a glomus caroticum tumor is associated with an increased sleepiness during the day. the carotid body is a chemoreceptor wich meassures the arteriel oxygen saturation en contributes to the regulation of the ventilation. A carotid body tumor may cause a disruption of the function of the chemoreceptor, wich may cause a less adequate ventiatoiry respons in hypoxic circumstances. This may contribute to an increase in sleepiness during the day with patients with head and neck paragangliomas, especially with the patients with a carotid body tumor.

Study objective

The objective of the study is to protract the sleep related complaints of patients with a carotid body tumor, especially with patients with a carotid body tumor. Patients will be divided in groups based on having a single sided or double sided GCT. And there will be a subdivision whterher or not the patient has been operated on the single- or double sided GCT.

Study design

the study is cross-sectional in design, to examine the causes of sleep related complaints with the help of polysomnografy

Study burden and risks

To participate in the study patients and control persons will be staying in the hospital for one day to perform the polysomnografy. They will have to visit the LUMC to have an instruction how to perform the sleep registration at home, they will have to visit the LUMC to bring back the equipment and they will were an actiwatch for two weeks. All of the meassurements are safe and non-invasive.

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

patients with carotid body tumors
informed consent
declaration of insent

Exclusion criteria

pregnancy
diagnosed sleeping disorder
instable regulation of blood pressure with respect to medication use
chronic use of sleep medication
psychotropic medication
existence of secondary paraganglioma of the thorax, abdomen or pelvis

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2009
Enrollment:	50

Type:	Actual

Ethics review

Approved WMO Date:	04-02-2009
Application type:	First submission
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	NL24518.058.08