Prevalence of Obstructive Sleep Apnea (OSA) after treatment for advance stage head and neck cancer

Published: 26-07-2018
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1. To evaluate the prevalence of obstructive sleep apnea (OSA) in patients after treatment for advanced stage head and neck cancer2. To identify subgroups with higher risk of OSA within this cohort (e.g. tumor site and treatment type)3. To evaluate...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Observational non invasive

Summary

ID

NL-OMON48756

Source
ToetsingOnline

Brief title
Prevalence of sleepapnea after treatment for head and neck cancer

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
obstructive sleep apnea, sleep apnea

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,Vivisol

Intervention

Keyword: Head and neck cancer, Obstructive Sleep Apnea, Prevalence

Outcome measures

Primary outcome

Prevalence of obstructive sleep apnea

Secondary outcome

Subgroups with a higher risk on obstructive sleep apnea and the difference in

quality of life between patients with and without obstructive sleep apnea

Study description

Background summary

Obstructive Sleep Apnea (OSA) has proven to be associated with significant morbidity and mortality. Since OSA seems to have a negative impact on quality of life, the recognition and treatment of OSA in head and neck cancer survivors may contribute to an improvement of their quality of life. However, accurate numbers on the extent of the problem among head and neck cancer patients and results on high risk subgroups lack.

Study objective

1. To evaluate the prevalence of obstructive sleep apnea (OSA) in patients after treatment for advanced stage head and neck cancer
2. To identify subgroups with higher risk of OSA within this cohort (e.g. tumor site and treatment type)
3. To evaluate the effect of OSA on quality of life of patients of this cohort
4. To evaluate the effect of treatment of OSA on quality of life of patients of this cohort

Study design

Prospective cross-sectional study

Study burden and risks

Not applicable

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

More than one year after treatment for T3-4 oral cavity, oropharynx, hypopharynx or larynx cancer.

Exclusion criteria

Not applicable

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-09-2019
Enrollment:	196
Type:	Actual

Ethics review

Approved WMO

Date:	26-07-2018
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	15-02-2019
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO

Date:	18-12-2019
Application type:	Amendment
Review commission:	METC NedMec

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	NL63971.031.17