Prospective cohort study on the prevalence of obstructive sleep apnea in patients with head and neck cancer treated with either radiotherapy, chemoradiation or surgery

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Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON33028

Source
ToetsingOnline

Brief title
prevalence of OSAS before and after treatment of head and neck cancer

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Upper respiratory tract disorders (excl infections)

Synonym
obstructive sleep apnea syndrome, sleep disordered breathing

Research involving
Human

Sponsors and support

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

Intervention

Keyword: head and neck cancer, obstructive sleep apnea syndrome (OSAS), treatment

Outcome measures

Primary outcome

Incidence of OSAS in 3 populations with Head and neck cancer

Secondary outcome

Influence of treatment on the OSAS

Study description

Background summary

Titel: *Prospective cohort study on the prevalence of obstructive sleep apnea in patients with head and neck cancer treated with either radiotherapy, chemoradiation or surgery*

Obstructive sleep apnea syndrome (OSAS) is the most common sleep disorder and increasingly recognised as a major health problem. The prevalence of OSAS in the middle aged population is 2% of women and 4% of men (1). In the Netherlands 40,000 men and 20,000 women suffer from OSAS (2).
OSAS is defined by the American Academy of Sleep Medicine Task Force (1999) as more than five obstructive apneas or hypopneas per hour of sleep and excessive daytime sleepiness, not explained by other factors, or two or more of the following symptoms: gasp for breath during sleep, repeated nocturnal awakening, non recuperative sleep, diurnal fatigue and altered concentration (3). The severity of OSAS is expressed in the apnea hypopnea index (AHI). An AHI of 5-15 is mild OSAS, an AHI of 15-30 is moderate and AHI >30 is severe OSAS, as assessed by polysomnography (4).
Unfortunately approximately 80% of OSAS patients remain undiagnosed and patients with atypical symptoms may go unrecognized (5,6). Awareness of the risk factors for the development of OSAS makes it possible to determine which patients should be screened for this condition.
OSAS is being treated because of its complaints, but also since it is becoming

increasingly clear that OSAS is associated with considerable comorbidity, including hypertension and increased risk for other cardiovascular diseases. Identification and treatment of OSAS may be an important factor in improving quality of life (7).

A growing body of literature is suggesting that there is a link between head and neck cancer treated with radiation therapy or surgery and the development of OSAS (6 - 18).

Study objective

The primary objective is to evaluate the percentage of the study population who have OSAS before and after treatment and the severity of it. A second objective is to correlate the prevalence of OSAS with different tumour sites and stages, as well as different treatments and to study the correlation between the different variables with OSAS.

Study design

prospective cohort study

Study burden and risks

Patients have to fill in a questionnaire and have to have 2 sleep registrations in the Lucas-Andreas Hospital.

No risks involved.

The possible benefit is that they are timely diagnosed with OSAS and can be treated.

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

T2-4 laryngeal carcinoma, treated with radiotherapy
T3-4 oral and oropharyngeal carcinoma treated with a commandoprocedure (with/without postoperative (chemo)radiation.)
T2-4 oro- or hypopharyngeal cancer treated with chemoradiation

Exclusion criteria

Age older than 18 or younger than 80
Stridor and need for tracheostomy before/during treatment
Inability to undergo polysomnography
Inability to complete questionnaires
Other conditions deemed by the Principle Investigator that make the subject ineligible for protocol procedures

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL28916.031.09