Evaluation of the airway changes in different degrees of severity of obstructive sleep apnea syndrome with 3-D airway computed tomography.

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Evaluation of the three-dimensional airway with a Conebeam CT(CBCT) scan to evaluate the upper-airway's in patientis with different degrees of severity of OSAS.

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

Summary

ID

NL-OMON32427

Source
ToetsingOnline

Brief title
3-D airway CT in patients with obstructive sleep apnea syndrome

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
OSAS, Sleepapneusyndrome

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 3D CT, airway volume, Conebeam CT, Obstructive Sleep Apnea Syndrome

Outcome measures

Primary outcome

3-D CT, total airway volume (mm3) and configuration of the oropharyngeal area,

minimal cross-sectional area and the localization of the minimal

cross-sectional area.

Secondary outcome

Patients treated with an MRD (Mandibular Repositioning Device) will be scanned

twice, with and withouth wearing the MRD. The primary study parameters with and

withouth MRD will be compared.

Study description

Background summary

The central research question: Is there an correlation between airway changes in volume and shape in patients with different degrees of severity of OSAS, Obstructive Sleep Apnea Syndrome?

OSAS is caused by an obstruction of the upper airway. The correlation between different degrees of severity of OSAS and the changes in the oropharyngeal area are not fully understood. The purpose of this study is to give a clearer image of the severity of obstruction of the oropharyngeal area and severity of OSAS.

Study objective

Evaluation of the three-dimensional airway with a Conebeam CT(CBCT) scan to evaluate the upper-airway's in patientis with different degrees of severity of OSAS.

Study design

A prospective series of 30 patients with OSAS will be studied with 3D-airway

CBCT.

Study burden and risks

Patients will undergo one or two CBCT scan's of the oropharyngeal area during one visit. The number of scans depend on the use of an MRD. One CB-CT scan will take 40 seconds and has no direct risks uposed upon the patient. A CBCT-scan is non-invasive and the extent of the burden for the patient will therefore be small. The advantage of the CBCT scan is the radiation tax, this tax is much higher in conventional CT-scanning. Long term risks depending on radiation tax are smaller.

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

clinical symptoms(>2); snoring, daytime somnolence and apnea with witness.
apnea-hypopneaindex(AHI) >5/hour

Exclusion criteria

clinical symptoms(<2); snoring, daytime somnolence and apnea with witness
apnea-hypopneaindex(AHI)<5/hour
patients with nasal, oral, pharyngeal or mandibular abnormalities or diseases.
patients with previous surgery in the pharynxregion
patients treated with CPAP, ten tijde van onderzoek.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-04-2009
Enrollment:	30
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	06-04-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL26388.091.08