Single Ring Optical Catheter illumination study in patients with obstructive Sleep Apnea during DISE

Published: 31-03-2016
Last updated: 19-04-2024

Primary objective of the study is to create one or multiple light ring(s) in the upper airway of OSA patients by means of Single Ring Optical Catheter(s), visualize and record these light rings with a DISE endoscope, capture the change of light ring...

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

Summary

ID

NL-OMON43702

Source
ToetsingOnline

Brief title
OC during DISE

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
sleepingdisorder with apnoeas

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: bedrijf;zie G2

Intervention

Keyword: DISE, optical catheter, OSA

Outcome measures

Primary outcome

Visuality of light ring projection on airway wall, configuration change during

collapse and separation between the light rings.

Secondary outcome

n.a.

Study description

Background summary

Drug Induced Sleep Endoscopy (DISE) represents the most widespread diagnostic tool for evaluation of the anatomical root cause of Obstructive Sleep Apnea (OSA) in patients. Disadvantages of DISE are that a patient needs to be sedated, OSA events are visualized during drug induced sleep instead of natural sleep, that events can only be monitored at one location at a time, and the examination is for a short period of time only. As a first step in developing an improved diagnostic device, a newly developed optical catheter will be used during DISE.

Study objective

Primary objective of the study is to create one or multiple light ring(s) in the upper airway of OSA patients by means of Single Ring Optical Catheter(s), visualize and record these light rings with a DISE endoscope, capture the change of light ring configuration during collapse of the airway and identify longitude and separation of collapse-critical sites in the human upper airway.

Study design

observational study

Study burden and risks

The risks for the subjects participating in this study are negligible. Burden to the healthy volunteers consists of an endoscopic examination of the upper airway and the insertion via a nostril of optical catheters for a maximum of thirty minutes. Burden to the OSA patients consists of a slighly longer sedation time following DISE. Both groups can possibly experience some temporary irritation of the upper airway wall after the procedure.

Contacts

Public
Philips

High Tech Campus 34
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NL
Scientific
Philips

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy subjects:
+ 18 years and older;OSA patients:
+ 18 years and older
+ diagnosis with moderate or severe OSA (AHI>15)

+ scheduled to undergo DISE

Exclusion criteria

Healthy subjects and OSA patients:
- morphological nasal airway abnormalities prohibiting entry of both nostrils by the endoscope or catheter
- nasal congestion prohibiting entry of both nostrils by the endoscope or catheter
- patients with suspected sensitivity to light, e.g. patients who had photodynamic therapy
-inability to provide informed consent
- pregnancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2017
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	31-03-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL55077.029.15