The value of biomarkers as diagnostic tool in Obstructive Sleep Apnea

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To identify biomarkers associated with OSA and OSA disease severity by investigating whether there are biomarkers in agreement with PSG, pre- and post-treatment and does OSA treatment result in improvement of these markers associated with...

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

Summary

ID

NL-OMON49507

Source
ToetsingOnline

Brief title
BiOSA

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
Sleepapnea, stop breathing

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: KFAS;koeweit

Intervention

Keyword: biomarkers, diagnosis, OSA, therapy

Outcome measures

Primary outcome

Changes in the selected biomarkers before and after OSA treatment.

Secondary outcome

Changes in AHI and subjective outcomes correlated to changes in biomarkers.

Study description

Background summary

Obstructive sleep apnea (OSA) is a problem of epidemic proportions. Even though accurate statistics are lacking, it*s roughly estimated that a 10-15% of the European population is suffering from it. OSA can be treated through a number of procedures like Continuous Positive Airway Pressure (CPAP), Maxillofacial Surgery (MMA), ENT Surgery, Upper Airway Stimulation (UAS), Mandibular Advancement Device (MAD), and Positional Therapy (PT). The effect of treatment can be established by repeated sleep studies. Although Polysomnography (PSG) is the gold standard for diagnosing OSA, repeating standard PSG*s in all patients is time consuming and expensive. The Dasman Diabetes Institute has a biomarker panel that has potential for monitoring the severity and treatment effect of OSA. Identification of a blood biomarker, collected from venepuncture, can provide a less expensive, less time consuming and more patient friendly diagnosic tool than PSG. Replacement of PSG for accurate biomarkers would provide a worldwide opportunity for all OSA clinics to simplify baseline and follow-up standard OSA screening.

Study objective

To identify biomarkers associated with OSA and OSA disease severity by investigating whether there are biomarkers in agreement with PSG, pre- and post-treatment and does OSA treatment result in improvement of these markers associated with cardiovascular and metabolic diseases.

Study design

Single center prospective case-control study.

Study burden and risks

Following the hospital protocol all patients visiting the hospital for OSA screening receive a PSG after which will be decided whether treatment is necessary. The best treatment option will be evaluated for every patient. After CPAP treatment and UAS, a post-treatment PSG is already standard performed. An additional procedure for this cohort will be plasma extraction prior and after treatment.

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

- 18 years and older

- Diagnosed with OSA confirmed by a PSG (AHI*30 events per hour)

Exclusion criteria

- Central sleep apnea syndrome (>50% of central apneas)
- Inability to provide informed consent

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	16-11-2020
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	09-07-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-05-2021

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL72652.100.20