# 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.

2 - The value of biomarkers as diagnostic tool in Obstructive Sleep Apnea 20-06-2025

#### 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

Public OLVG

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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

3 - The value of biomarkers as diagnostic tool in Obstructive Sleep Apnea 20-06-2025

- 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
Туре:	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: Review commission: Amendment 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 CCMO ID NL72652.100.20