The DREAMS study: A prospective observational study on the first weeks of PAP treatment for obstructive sleep apnea

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The aim of this study is to evaluate the PAP treatment response in OSA patients during the first three weeks by monitoring the relevant objective and subjective sleep parameters.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON56944

Source
ToetsingOnline

Brief title
A prospective observational study on PAP treatment

Condition

- Other condition

Synonym
Sleep apnea, sleep disordered breathing

Health condition

slaapstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Kempenhaeghe
Source(s) of monetary or material Support: HTSM/STW,Philips

Intervention

Keyword: CPAP, Multi-night, Obstructive sleep apnea, Wearable sensors

Outcome measures

Primary outcome

Patient demographics and medical information, treatment information (e.g., PAP

readout), wearable-derived sleep parameters

Secondary outcome

Ambulatory PSG/PG/Watchpad-derived parameter, digital sleep diary,

questionnaires

Study description

Background summary

The most common treatment for OSA patients is positive airway pressure (PAP). Most assessments of PAP-treatment are restricted to polysomnnography measurement of a single night in the laboratory or sometimes at home. However, it has been shown that many sleep parameters show a high night-to-night variability. Therefore, a single-night measurement is likely not representative of the patients regular sleeping patterns. Multi-night monitoring is needed to overcome the limitations of previous research, to assess the night-to-night variability of various sleep parameters and to assess the treatment response more effectively. Recent advancements in wearable sensor technology have opened up new opportunities to unobtrusively measure sleep for multiple nights in the patient*s home.

Study objective

The aim of this study is to evaluate the PAP treatment response in OSA patients during the first three weeks by monitoring the relevant objective and

subjective sleep parameters.

Study design

This is a prospective observational study in patients who are diagnosed with OSA at Maxima Medical Center and will be receiving PAP treatment for the first time. Participants in this study will receive routine clinical care. Additionally, they will receive three additional measurements as part of this study: A wearable sensor, a digital sleep diary, and several questionnaires. The participants are asked to wear the wearable sensor during the night and to complete the digital sleep diary questions during the first three weeks of PAP treatment. In addition, the participants are three times asked to fill in several questionnaires: After one day, three and 14 weeks of PAP-treatment.

Study burden and risks

There are minimal risks for participants in this study. Participants may sometimes experience skin irritation when wearing the sensor (for too long) or may experience discomfort due to wearing the sensor during the night. This risk is acceptable, and the chance of this occurring is small. The wearable sensor is CE marked and extensively tested. In addition, the participants can take off the wearable sensor in case it causes skin irritation.

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

• Age older than 18
• Diagnosis of OSA
• Speaking and reading Dutch
• Written informed consent
• PAP treatment is prescribed for the first time
• Attend a PAP-initiation meeting
• PSG, PG or WatchPAT recording available
• Online intake questionnaire available

Exclusion criteria

• Suspicion of complex comorbid (sleep)disorders (as indicated by the clinical sleep expert).
• (Suspicion of) underlying severe neurological or psychiatric disorders, presence of persistent heart rhythm disorders, presence of autonomic dysfunction.
• Known allergies for hard plastic (like in sport watches) or wristband material
• Presence of wounds, injuries, or inflammation on the skin where the wristband will be placed
• Tattoo on top of the wrist or head (where the sensor should be placed)
• Pregnancy
• Working in (rotating) night shifts
• Inability to adhere to the study protocol

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	150
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	06-08-2024
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL87242.015.24