# Alternative APAP Method for Non-invasive Positive Airway Pressure Therapy in OSAHS patients. Amendment: Mallampati score as a predictor for effective Positive Airway Pressure

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1. To investigate whether an adjusted mode of APAP can improve patients adherence in comparison to fixed CPAP in present-day PAP therapy of OSAHS patients.2. To investigate the agreement between the parameters of the CPAP devices and the polygraphy...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Upper respiratory tract disorders (excl infections) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON36517

**Source**
ToetsingOnline

**Brief title**
RAPAP-study

### Condition

- Upper respiratory tract disorders (excl infections)

**Synonym**
Obstructive Sleep Apnea-Hypopnoea Syndrome

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Medisch Spectrum Twente
**Source(s) of monetary or material Support:** Medisch Spectrum Twente

## Intervention

**Keyword:** Continuous positive airway pressure, Restricted autoadjustable positive airway pressure, Sleep apnoea

## Outcome measures

### Primary outcome

The primary outcome measure is patient*s adherence for treatment modes. It is measured by recording the amount of sleeping time per night in hours with the PAP device.

Amendement: Regression formula predicting the optimal pressure setting for sleep apnea patients for the population that was investigated and may be extrapolated to sleep apnea patients overall.

### Secondary outcome

Secondary outcomes are: subjective: sleepiness (Epworth Sleepiness Score), quality of life (disease specific: Quebec Sleep Questionnaire, and generic: SF-36), preference for treatment mode and tolerance, and objective: polygraphy with both PAP treatment modes and by downloading data (AHI) of the PAP device.

# Study description

### Background summary

Obstructive Sleep Apnea-Hypopnoea Syndrome (OSAHS) is characterized by repetitive episodes of airflow reduction due to pharyngeal narrowing. The lack of adequate alveolar ventilation results in oxygen desaturation. This desaturation is resolved by an arousal from deep sleep to reopen the airway. The mainstay of medical treatment of OSAHS is administration of non-invasive positive airway pressure (PAP) therapy during sleep. Two kinds of PAP devices are available, the continuous PAP (CPAP) device and the auto-adjusted PAP (APAP) pressure.

The intention is to reduce mean applied pressures during the night which could increase acceptance and adherence with chronic PAP treatment. The pressure can be decreased by restricting the APAP pressure range around the effective pressure range.

In literature hardly any research is done to restrict the APAP (RAPAP) pressure. In this study the hypothesis is tested, if a new adjusted mode of APAP can approach an effective pressure range of limited APAP pressures to lower the mean applied pressure so adherence and acceptance will increase, and adverse effects will decrease. By comparison of a fixed CPAP mode with a restricted APAP range, this study aims to improve subjective and objective sleep parameters in OSAHS patients.

Amendment: Mallampati score is a well-known predictor for the development of sleep apnea. The same applies for the availability of retrognathia. It is very likely that these factors can tell us something about the amount of pressure that is needed to treat patients with sleep apnea.

**Study objective**

1. To investigate whether an adjusted mode of APAP can improve patients adherence in comparison to fixed CPAP in present-day PAP therapy of OSAHS patients.
2. To investigate the agreement between the parameters of the CPAP devices and the polygraphy measurement with CPAP.

Amendment: Find out if Mallampati score and retrognathia are factors that combined with BMI, neck circumference and amount of breathing cessations an hour, can predict the effective treatment pressure for sleep apnea patients.

**Study design**

The design of this study will be a single centre cross-over single blind study at the Medisch Spectrum Twente locations Enschede and Oldenzaal.

**Intervention**

Participating subjects will receive randomly two modes of PAP-therapy. One PAP mode will be given constant pressure (CPAP) and the other mode will deliver restricted APAP treatment (RAPAP). Both treatment modes will be delivered with the same REMstar Auto. The initial pressure level of the PAP-therapy is derived from manual CPAP titration polysomnography.

Amendment: The same population group will come to the hospital once again and the Mallampati score and availability of retrognathia is scored. Also a digital photograph is taken to ensure digital comparison and to express Mallampati score in surface units and retrognathia in distance instead of just positive or negative.

**Study burden and risks**

The risk for adverse events in this study is negligible. The CPAP treatment is conducted for years at mild to severe OSAS patients without occurrence of any (serious) adverse events. The operational algorithms are identical in their pressure adjustment even despite the adjustments made in the RAPAP mode. The pressure adjustment is limited to the range of pressures that is indicated. Since the range is smaller than the APAP, we do not suspect any risks.

# Contacts

**Public**
Universiteit Twente

Haaksbergerstraat 55
7513 ER Enschede
NL
**Scientific**
Universiteit Twente

Haaksbergerstraat 55
7513 ER Enschede
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Subjects of 18 years or older
PAP-therapy naive patients with confirmed OSAHS
Moderate OSAHS - AHI 15 - 30 events/hours and a least mild sleepiness
Severe OSAHS - AHI > 30 events/hours and at leat mild sleepiness
Moderate to severe sleepiness with AHI > 5 events/hours
Able to understand, read and write Dutch

## Exclusion criteria

Central sleep apnea syndrome
Cheyne-Stokes respiration
Signs of severe nasal obstruction
Major facial or pharyngeal anatomic abnormalities likely to require surgery.
Previous surgical treatment of UPPP
Night or rotating shift work
Severe chronic heart failure class IV
Chronic Obstructive Pulmonary Disease defined by the GOLD-criteria stage 3 to 4 (i.e., forced expiratory volume in 1 s [FEV1]/forced vital capacity [FVC] < 65%)
Known history of a known cause of daytime sleepiness and severe sleep disruption (e.g. insomnia, PLMS, narcolepsy)
Seizure disorder
Mental retardation
Psychiatric patients
Memory disorders
Pregnant patients
The inability to provide informed consent

# Study design

## Design

Study type: Interventional

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|---|---|
| Intervention model: | Crossover |
| Masking: | Single blinded (masking used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 14-07-2010 |
| Enrollment: | 33 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | Auto-adjustable and continuous positive airway pressure |
| Registration: | Yes - CE intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 03-06-2010 |
| Application type: | First submission |
| Review commission: | METC Twente (Enschede) |
| Approved WMO Date: | 25-10-2011 |
| Application type: | Amendment |
| Review commission: | METC Twente (Enschede) |

## 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 | NL31459.044.10 |