

# Management of the obstructive sleep apnea-hypopnea syndrome: oral appliance versus continuous positive airway pressure therapy

<b>Submission date</b> 12/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/09/2013	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr A. Hoekema

**Contact details**  
Department of Oral and Maxillofacial Surgery  
University Medical Center Groningen  
University of Groningen  
Hanzeplein 1  
P.O. Box 30001  
Groningen  
Netherlands  
9700 RB  
+31 (0)50 3613840  
a.hoekema@kchir.umcg.nl

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

### Study objectives

Primary aim of the randomised trial is to elucidate the efficacy of, respectively, Oral Appliance (OA) and Continuous Positive Airway Pressure (CPAP) therapy in the management of the Obstructive Sleep Apnea-Hypopnea Syndrome (OSAHS). It is hypothesised that OA and CPAP therapy are equivalent with respect to the successful management of OSAHS.

Secondary aims of the randomised trial are to elucidate:

1. Prognostic variables of the therapeutic efficacy of OA and CPAP therapy, respectively.
2. Co-morbidity of OA therapy.
3. The therapeutic effect of OA and CPAP therapy, respectively, on OSAHS related co-morbidity (neurobehavioral dysfunction, deviant driving performance, cardiovascular disease, sexual dysfunction).

Further information in: <http://www.ncbi.nlm.nih.gov/pubmed/15187032>

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the local medical ethics committee

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Obstructive Sleep Apnea-Hypopnea Syndrome (OSAHS)

### Interventions

1. Oral Appliance (OA) therapy
2. Continuous Positive Airway Pressure (CPAP) therapy

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Number of OSAHS patients successfully treated as a result of OA or CPAP therapy.

**Secondary outcome measures**

Improvements in:

1. Polysomnographic indices
2. Neurobehavioral outcomes (e.g. Short Form health survey [SF-36], Functional Outcomes of Sleep Questionnaire [FOSQ], Epworth Sleepiness Scale [ESS], Hospital Anxiety and Depression Scale [HADS])
3. Simulated driving performance
4. Cardiovascular outcomes (e.g. B-type Natriuretic Peptide [BNP])
5. Sexual dysfunction (e.g. Golombok-Rust Inventory of Sexual Satisfaction [GRISS])

**Overall study start date**

01/09/2002

**Completion date**

28/04/2005

**Eligibility****Key inclusion criteria**

Newly diagnosed OSAHS patients (over 20 years old) (i.e. criterion 1 and/or 2, plus criterion 3):

1. Excessive daytime sleepiness that is not better explained by other factors (Epworth Sleepiness Scale more than or equal to ten)
2. Two or more of the following symptoms that are not better explained by other factors:
  - a. choking or gasping during sleep
  - b. recurrent awakenings from sleep
  - c. unrefreshing sleep
  - d. daytime fatigue
  - e. impaired concentration
3. Overnight monitoring demonstrating an Apnea-Hypopnea Index (AHI) more than five

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

## **Target number of participants**

102

## **Key exclusion criteria**

### **I. Exclusion criteria:**

#### **1. Patients previously treated by:**

- a. CPAP
- b. OA
- c. uvulopalatopharyngoplasty

#### **2. Morphological upper airway abnormalities requiring treatment:**

- a. compromised nasal passage
- b. enlarged tonsils/ adenoids
- c. soft tissue- or craniofacial abnormalities in upper airway
- d. upper airway neoplasm

#### **3. Endocrine dysfunction:**

- a. acromegaly
- b. hypothyroidism

#### **4. Co-morbidity:**

- a. daytime respiratory insufficiency
- b. severe Chronic Obstructive Pulmonary Disease (COPD) (Forced Expiratory Volume in one second (FEV1)/Vital Capacity (VC) less than 40%)
- c. left ventricular failure
- d. severe daytime cardiac arrhythmias

#### **5. Psychological condition precluding informed consent:**

- a. psychiatric diseases (eg depression, schizophrenia)
- b. mental retardation

### **II. Dental exclusion criteria:**

- 1. Severe periodontal disease or dental decay
- 2. 'Active' temporomandibular joint disease (including severe bruxism)
- 3. Restrictions in mandibular opening or protrusion capacity:
  - a. mouth opening less than 25 mm
  - b. maximal protrusion mandible less than 5 mm
- 4. Partial or complete edentulism:
  - a. Less than eight teeth in upper or lower jaw

### **III. Patients declining written informed consent**

## **Date of first enrolment**

01/09/2002

## **Date of final enrolment**

28/04/2005

## **Locations**

## **Countries of recruitment**

Netherlands

**Study participating centre**  
Department of Oral and Maxillofacial Surgery  
Groningen  
Netherlands  
9700 RB

## Sponsor information

**Organisation**  
University Medical Center Groningen (The Netherlands)

**Sponsor details**  
University of Groningen  
Department of Oral and Maxillofacial Surgery  
Hanzeplein 1  
Groningen  
Netherlands  
9713 GZ

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.umcg.nl/azg/nl/english/azg/>

**ROR**  
<https://ror.org/03cv38k47>

## Funder(s)

**Funder type**  
Research organisation

**Funder Name**  
Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

**Alternative Name(s)**  
Netherlands Organisation for Health Research and Development

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Other non-profit organizations

**Location**

Netherlands

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2013		Yes	No