

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

Submission date 12/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 12/09/2005	Overall study status Completed	☐ Protocol
Last Edited 03/09/2013	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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])

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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)

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

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?
Results article	results	01/09/2013		Yes	No