Management of the Obstructive Sleep Apnea-Hypopnea Syndrome: Oral Appliance versus Continuous Positive Airway Pressure Therapy.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22799

Source
NTR

Brief title
N/A

Health condition

Obstructive Sleep Apnea-Hypopnea Syndrome (OSAHS).

Sponsors and support

Primary sponsor: Drs. A. Hoekema
Prof. Dr. B. Stegenga
Prof. Dr. LGM de Bont
Drs. A.F. Meinesz
Dr. P.J. Wijkstra
Dr. J.H. van der Hoeven
Dr. M.F. van Driel
Source(s) of monetary or material Support: Financial support for a MD-clinical research traineeship was granted by the Netherlands Organisation for Health Research and Development.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Improvements in:

1. polysomnographic indices;

2. neurobehavioral outcomes (e.g. SF-36, FOSQ, ESS, HADS);

3. simulated driving performance;

4. cardiovascular outcomes (e.g. BNP);

5. sexual dysfunction (e.g. GRISS).

Study description

Background summary

The Obstructive Sleep Apnea-Hypopnea Syndrome (OSAHS) is common sleep disorder with life threatening sequelae. Continuous Positive Airway Pressure (CPAP) therapy ¡± is currently regarded as the treatment standard for OSAHS. Besides CPAP, dental devices known as Oral Appliances (OA¡¯s) have been of significance in the treatment of this sleep related breathing disorder. However, the evidence-base with respect to the efficacy and co-morbidity of OA therapy in the management of OSAHS is still insufficient.
Primary aim of the present randomised trial is to elucidate the efficacy of, respectively, OA and CPAP therapy in the management of OSAHS. In order to do so eligible OSAHS patients are randomised for either OA or CPAP therapy and followed for a two year period.
On the basis of the study results we hope to elucidate the therapeutic efficacy and the specific indication for, respectively, OA and CPAP therapy in the management of OSAHS. A secondary aim is to find possible prognostic variables for the therapeutic efficacy of OA and CPAP therapy. In addition, we hope to elucidate the co-morbidity of Oral Appliance therapy and explore the therapeutic effect of OA and CPAP therapy on OSAHS related co-morbidity (neurobehavioral dysfunction, deviant driving performance, cardiovascular disease and sexual dysfunction).

Study objective

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 hypothesized that OA and CPAP therapy are equivalent with respect to the successful management of OSAHS.
Secondary aims of the randomised trial are to elucidate:

- prognostic variables of the therapeutic efficacy of OA and CPAP therapy, respectively.

- co-morbidity of OA therapy.

- the therapeutic effect of OA and CPAP therapy, respectively, on OSAHS related co-morbidity (neurobehavioral dysfunction, deviant driving performance, cardiovascular disease, sexual dysfunction).

Study design

N/A

Intervention

1. Oral Appliance (OA) therapy;

2. Continuous Positive Airway Pressure (CPAP) therapy.

Contacts

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Eligibility criteria

Inclusion criteria

1. Newly diagnosed OSAHS patients (i.e. criterion A and/or B, plus criterion C):

a. Excessive daytime sleepiness that is not better explained by other factors (Epworth Sleepiness Scale ¡Ý 10).

b. Two or more of the following symptoms that are not better explained by other factors;

-choking or gasping during sleep

-recurrent awakenings from sleep

-unrefreshing sleep

-daytime fatigue

-impaired concentration

c. Overnight monitoring demonstrating an Apnea-Hypopnea Index (AHI) > 5.

2. Patients older than 20 years of age

Exclusion criteria

I. Exclusioncriteria

1. Patients previously treated by:

-CPAP

-OA

-uvulopalatopharyngoplasty;

2. Morphological upper airway abnormalities requiring treatment:

-compromised nasal passage

-enlarged tonsils/ adenoids

-soft tissue- or craniofacial abnormalities in upper airway

- upper airway neoplasm;

3. Endocrine dysfunction:

-acromegaly

-hypothyrodism;

4. Co-morbidity:

-daytime respiratory insufficiency

-severe COPD (FEV1/VC <40%)

-left ventricular failure

-severe daytime cardiac arrhythmias;

5. Psychological condition precluding informed consent:

-psychiatric diseases (eg depression, schizofrenia)

-mental retardation;

II. Dental exclusioncriteria

6. Severe periodontal disease or dental decay;

7. ¡°Active¡± temporomandibular joint disease (including severe bruxism);

8. Restrictions in mandibular opening- or protrusion capacity:

-mouth opening <25 mm

-maximal protrusion mandible <5 mm

9. Partial or complete edentulism:

-<8 teeth in upper- or lower jaw;

III. Patients declining written informe
d consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2002
Enrollment:	102
Type:	Actual

Ethics review

Positive opinion

Date:	02-08-2005
Application type:	First submission

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
NTR-new	NL75
NTR-old	NTR106
Other	: N/A
ISRCTN	ISRCTN18174167

Study results

Summary results

1. Sleep Breath. 2006 Jun;10(2):102-3.

2. Hoekema A, Stegenga B, de Bont LGM. Efficacy and Co-Morbidity of Oral Appliances in the Treatment of Obstructive Sleep Apnea-Hypopnea: a Systematic Review. Crit Rev Oral Biol Med 2004;15 (3):137-155.
