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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22799

Bron
NTR

Verkorte titel
N/A

Aandoening

Obstructive Sleep Apnea-Hypopnea Syndrome (OSAHS).

Ondersteuning

Primaire sponsor: Drs. A. Hoekema
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Overige ondersteuning: Financial support for a MD-clinical research traineeship was

granted by the Netherlands Organisation for Health Research and Development.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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).

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

1. Oral Appliance (OA) therapy;

2. Continuous Positive Airway Pressure (CPAP) therapy.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2002
Aantal proefpersonen:	102
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	02-08-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL75
NTR-old	NTR106
Ander register	: N/A
ISRCTN	ISRCTN18174167

Resultaten

Samenvatting resultaten
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.
