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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

Registration date
12/09/2005

Overall study status
Completed

Last Edited
03/09/2013

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] 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

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. hypothyrodism
4. Co-morbidity:
a. daytime respiratory insufficiency
b. severe Chronic Obstructive Pulmonary Disease (COPD) (Forced Expriatory 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, schizofrenia)
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
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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?
Results article	results	01/09/2013		Yes	No