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Positive airway pressure in older people: a randomised controlled trial

Submission date
11/06/2008

Recruitment status
No longer recruiting

Registration date
18/06/2008

Overall study status
Completed

Last Edited
10/03/2016

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Obstructive sleep apnoea hypopnoea syndrome (OSAHS) is the name given to difficulty in breathing during sleep due to blockage of the airway behind the tongue. It causes profound daytime sleepiness, high blood pressure, an increased risk of heart attack/stroke and possibly memory problems. OSAHS is the third most common respiratory disorder, after asthma and chronic obstructive pulmonary disease, affecting 2 - 4% of middle aged people. In older people prevalence is almost 10 times greater, with up to 20% of older people having OSAHS. OSAHS can be treated with continuous positive airway pressure (CPAP). A CPAP device delivers compressed air through a mask covering the nose and mouth, which prevents the throat from closing. A recent report concluded that CPAP is an extremely cost effective treatment for OSAHS in middle-aged people. Unfortunately the beneficial effects of CPAP cannot be presumed to be the same in older people because the causes and consequences of the disease change with age. Very little information is available for doctors and healthcare professionals regarding the best way to treat OSAHS in older people. This study will measure the effect of treating OSAHS on sleepiness and other health-related factors, such as risk factors for heart disease and memory function, in patients over 65 years old.

Who can participate?
Patients aged over 65 with OSAHS

What does the study involve?
Participants are randomly allocated to be treated with either CPAP or a best supportive care package (consisting of advice, a general medical review and heart disease risk assessment). Both groups are monitored for 12 months, particularly their use of healthcare facilities, to show whether CPAP effectively treats older people with OSAHS and whether it is cost effective.

What are the possible benefits and risks of participating?
The UK population is ageing, thereby increasing the burden of disease. One of the best ways to reduce these costs is to maintain the independence of older people. Treating OSAHS appropriately in older people will benefit both individual patients and reduce the economic burden of disease in the UK.

Where is the study run from?
Churchill Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2009 to May 2012

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Magda Laskawiec

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 08/56/02

Study information

Scientific Title
A randomised controlled trial of continuous positive airway pressure treatment in older people with obstructive sleep apnoea/hypopnoea syndrome

Acronym
PREDICT

Study objectives
This study will measure the effect of treating obstructive sleep apnoea hypopnoea syndrome (OSAHS) with continuous positive airway pressure (CPAP) on sleepiness and other health related factors, such as risk factors for heart disease and memory function, in patients over 65 years old.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/085602
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0015/53007/PRO-08-56-02.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brompton, Harefield and NHLI Research Ethics Committee, 22/05/2009, ref: 09/H0708/33

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Sleep apnoea

Interventions
Treatment (Continuous positive airway pressure) limb
Obstructive sleep apnoea will be diagnosed from a diagnostic overnight polysomnographic sleep study. After trial entry, subjects assigned to CPAP therapy will be started on self-adjusting nasal CPAP therapy (AutoSet®, ResMed Plc). This therapy automatically adjusts airway pressure to be sufficient to prevent snoring and sleep apnoea without being excessive. The initiation of this therapy will be in keeping with the recruiting centres normal clinical practice (and minimisation by centre at trial entry will ensure that subjects with slightly varying CPAP initiation protocols are evenly distributed between the trial groups). At months 3 and 12 of trial follow-up the stored memory of the CPAP machines will be interrogated to define treatment efficiency over multiple nights. This will define how well sleep apnoea has been controlled over time in the intervention group. Overnight arterial pulse oximetry recording will be performed to quantify sleep apnoea control on one night in both trial groups. The active treatment limb will also receive the best supportive care package.

Control limb (Best supportive care only)
Best supportive care will consist of:
1. Advice on minimising daytime sleepiness through sleep hygiene and advice about using the nap/caffeine assaults management strategy
2. Advice on weight loss strategies
3. A general medical review to confirm optimal healthcare for any co-morbid conditions
4. Cardiovascular risk assessment with intervention (co-ordinated through the General Practitioner) to minimise vascular risk. Consistent with national guidelines.

Total duration of interventions and follow-up: 12 months

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The following will be measured throughout the whole of the 12-month trial period:
1. Subjective sleepiness: average weekly Epworth Sleepiness Scale (ESS)
2. Health economic analysis: measured from health care utilisation and cost utility analysis using the EQ-5D

Secondary outcome measures
Current secondary outcome measures as of 07/04/2010:
The following will be measured throughout the whole of the 12-month trial period:
1. Objective sleepiness: Oxford Sleep Resistance Test (OSLER) maintenance of wakefulness test (x 2 morning tests)
2. Self reported health status (quality of life and mood): 36-item Short Form questionnaire (SF-36), and Sleep Apnoea Quality of Life Index (SAQLI; a disease specific sleep apnoea questionnaire which includes CPAP side effects), Hospital Anxiety and Depression Scale (HADS)
3. Functional index of activities of daily living: Townsend Disability Scale (TDS)
4. Frequency of nocturia: Self reported using the patient [monthly] diary
5. Mobility: Timed to up and go test
6. Accidents: Including self-reported road accidents and domestic accidents
7. Cognitive function: Mini-mental state, Trail making B time, the Digit Symbol Substitution test, simple and four-choice reaction time
8. Cardiovascular Risk Index: Change in combined stroke and myocardial infarction risk measured by the Framingham vascular risk index, which includes office blood pressure, cholesterol, smoking status, hyperglycaemia
9. Adverse cardiovascular events: Myocardial infarction, stroke, transient ischemic attack, new angina, new atrial fibrillation, new peripheral vascular disease

Previous secondary outcome measures at time of registration:
The following will be measured throughout the whole of the 12-month trial period:
1. Objective sleepiness: measured using the maintenance of wakefulness test of the Oxford sleep resistance test (OSLER)
2. Self-reported health status (quality of life): the 36-item Short Form health survey (SF-36), CASP-19, the Short Sleep Apnea Quality of Life Index (SAQLI) questionnaire (which includes CPAP side effects)

3. Accidents, including road accidents
4. Change in combined stroke and myocardial infarction risk: measured by the Framingham Index
5. Individual components of the Framingham vascular risk index; blood pressure, cholesterol, smoking, glycaemia
6. Myocardial infarction/ stroke/ vascular event rate, left ventricular hypertrophy (ECG)
7. Cognitive function
8. Systemic inflammatory status
9. Functional index of activities of daily living (Townsend disability scale)

Overall study start date
01/02/2009

Completion date
31/05/2012

Eligibility

Key inclusion criteria
Current inclusion criteria as of 07/04/2010:
1. Aged greater than 65 years, either sex
2. A clinical diagnosis of OSAHS: more than/equal to 4% oxygen desaturation index greater than 7.5 events/hour and an Epworth sleepiness scale more than/equal to 9
3. Ability to give written informed consent

Previous inclusion criteria at time of registration:
1. Both males and females, aged greater than 65 years
2. Apnoea hypopnoea index greater than or equal to 15 events/hour of sleep on multi-channel sleep study, and at least two symptoms of excessive daytime sleepiness or Epworth sleepiness scale greater than or equal to 11
3. Written informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
278

Key exclusion criteria
1. Previous exposure to nasal CPAP therapy
2. Arterial oxygen saturation less than 93%
3. Forced expiratory volume in one second (FEV1) less than 65% predicted
4. Substantial problems with sleepiness driving (in those who are still driving); currently using Heavy Goods Vehicle (HGV) or Public Service Vehicle (PSV) driving licence (where applicable)
5. Shift work

6. Inability to give informed consent or comply with the protocol
7. Irreversible visual impairment

Date of first enrolment
01/02/2009

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Churchill Hospital
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Sponsor information

Organisation
University of Oxford (UK)

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Clinical Trials and Research Governance (CTRG)
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Sponsor type
University/education

Website
http://www.ox.ac.uk

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/10/2014		Yes	No
Results article	results	01/06/2015		Yes	No