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Effect of continuous positive airway pressure (CPAP) therapy on arterial stiffness in patients with obstructive sleep apnoea/hypopnoea syndrome (OSAHS)

Submission date
07/07/2010

Registration date
27/07/2010

Last Edited
02/12/2013

Recruitment status
No longer recruiting

Overall study status
Completed

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

PG/06/092/21267

Study information

Scientific Title
Aortic distensibility in obstructive sleep apnoea/hypopnoea syndrome (OSAHS) using cardiovascular magnetic resonance imaging and and pulse wave analysis: effect of continuous positive airway pressure (CPAP) therapy

Study objectives
Obstructive sleep apnoea/hypopnoea syndrome (OSAHS) affects 1 - 4 % of the middle-aged population causing excessive daytime sleepiness. A greater proportion of the population will exhibit sleep disordered breathing, but will not complain of excessive daytime sleepiness. OSAHS is associated with a significantly increased risk of cardiovascular disease and hypertension. The causes of this are likely to be multifactorial and may include repeated oxygen desaturations or factors associated with the excessive daytime sleepiness. Postulated mechanisms for this increased risk include increased arterial stiffness and endothelial dysfunction, which can be measured non-invasively using applanation tonometry (pulse wave velocity and analysis) and cardiovascular magnetic resonance imaging (MRI). Continuous positive airway pressure (CPAP) therapy is an established treatment for OSAHS and is useful in reducing symptoms, it has also been shown to reduce blood pressure in sleepy patients with OSAHS.

This study aims to measure the effect that CPAP therapy has upon arterial stiffness and endothelial function in patients with OSAHS. By studying patients with varying degrees of OSAHS, both in terms of nocturnal oxygen desaturation and levels of daytime sleepiness, but without known cardiovascular disease we hope to further examine the factors that are important in determining arterial stiffness and endothelial dysfunction in these patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lothian Local Research Ethics Committee 02, 24/01/2007, ref: 06/S1102/54

Study design
Randomised double blind placebo-controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Obstructive sleep apnoea/hypopnoea syndrome (OSAHS)

Interventions
Patients meeting the inclusion criteria will be recruited from the Department of Sleep Medicine. This is a randomised controlled crossover trial with 12 weeks in each limb. The active treatment limb consists of CPAP set to provide optimal pressures for treatment and the placebo limb utilises sham CPAP set to provide a sub-optimal pressure. At baseline and after each limb of the study patients will undergo the following measurements:
1. Pulse wave velocity (PWV) and pulse wave analysis (PWA) - before and after administration of GTN and salbutamol
2. Cardiovascular MRI of aorta
3. Blood pressure recording
4. Epworth Sleepiness Score

Control subjects will undergo the above investigations once.

Patients spent approximately 12 weeks in each limb; total duration of treatment is therefore approximately 24 weeks in total for intervention group. Control subjects were assessed once and there was no further follow up after this.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Arterial stiffness as measured by PWV/PWA and aortic distensibility as measured by cardiovascular MRI, at timepoints 0, 12 and 24 weeks

Secondary outcome measures
Measured at timepoints 0, 12 and 24 weeks:
1. Endothelial function as measured by pulse wave analysis (before and after administration of GTN and salbutamol)
2. Blood pressure changes

Overall study start date
01/02/2007

Completion date
04/08/2009

Eligibility

Key inclusion criteria

Both:
1. Males and females aged 18 - 65 years

Patients:
2. Apnoea Hypopnoea Index (AHI) greater than or equal to 15 at polysomnography
3. CPAP naive
4. Ability to give written informed consent

Control subjects:
5. AHI less than or equal to 10 at polysomnography
6. Epworth Sleepiness Score (ESS) less than 11
7. Ability to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
80 (including 60 patients with varying severity of disease and 20 controls)

Key exclusion criteria
1. Inability to give written informed consent
2. Known cardiovascular disease or diabetes
3. History of respiratory failure
4. Medications affecting blood pressure
5. Reported sleepiness when driving or those who drive for a living
6. Claustrophobia precluding magnetic resonance imaging (MRI) scanning
7. Implanted/foreign bodies precluding MRI scanning

Date of first enrolment
01/02/2007

Date of final enrolment
04/08/2009

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Department of Sleep Medicine
Edinburgh
United Kingdom
EH16 4SA

Sponsor information

Organisation
University of Edinburgh (UK)

Sponsor details
Queen's Medical Research Institute
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Sponsor type
University/education

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

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF) (UK) (ref: PG/06/092/21267)

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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	01/05/2013		Yes	No
Results article	results	01/12/2013		Yes	No