

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/12/2013	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Renata Riha

Contact details

Department of Sleep Medicine
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

Additional identifiers

Protocol serial number

PG/06/092/21267

Study information

Scientific Title

Aortic distensibility in obstructive sleep apnoea/hypopnoea syndrome (OSAHS) using cardiovascular magnetic resonance imaging 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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**

United Kingdom

Scotland

Study participating centre

Department of Sleep Medicine

Edinburgh

United Kingdom

EH16 4SA

Sponsor information**Organisation**

University of Edinburgh (UK)

ROR

<https://ror.org/01nrxf90>

Funder(s)

Funder type

Charity

Funder Name

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

Alternative Name(s)

The British Heart Foundation, the_bhf, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

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