ISRCTN34164388 https://doi.org/10.1186/ISRCTN34164388

Multi-centre randomised controlled trial to investigate the efficacy of nasal continuous positive airway pressure treatment to reduce cardiovascular risk and symptoms in mild to moderate sleep apnoea

Submission date	Recruitment status	[X] Prospectively registered
16/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/10/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/03/2016	Nervous System Diseases	

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=19

Contact information

Type(s)
Scientific

Contact name
Prof John Stradling

Contact details
Oxford Sleep Unit
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MOSAIC 1

Study information

Scientific Title
Multi-centre randomised controlled trial to investigate the efficacy of nasal continuous positive airway pressure treatment to reduce cardiovascular risk and symptoms in mild to moderate sleep apnoea

Acronym
Multi-centre Obstructive Sleep Apnoea Interventional Cardiovascular Trial (MOSAIC)

Study objectives
Patients with Obstructive Sleep Apnoea (OSA) are treated with nasal continuous positive airway pressure (CPAP) to control excessive daytime sleepiness, and to reduce vascular risk by improving blood pressure (BP), and possibly other vascular risk factors. Randomised trials for one month have shown falls in BP following treatment for disease at the more severe end of the spectrum, but not for less severe disease where treatment benefits are currently unproven. If the treatment of less severe disease produces similar benefits, this will be a substantial therapeutic advance in vascular risk reduction, since this disease affects up to 6% of men. If ineffective, the substantial treatment costs would be better directed elsewhere. The randomised trial proposed here will determine whether treating less severe sleep apnoea reduces calculated vascular risk, surrogate measures of cardiovascular disease, symptomatic benefits, and will determine the feasibility of a subsequent phase 3, long-term, trial to quantify any actual reduction in vascular event rate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxfordshire REC A, 15/12/2005, ref: 05/Q1604/159

Study design
Multi-centre randomised controlled

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
Sleep apnoea

Interventions
Nasal CPAP machines versus no intervention

Intervention Type
Device

Primary outcome measure
1. Reduction in the cardiovascular risk using the Framingham score
2. Reduction in Epworth Sleepiness Score

Secondary outcome measures
1. Fall in insulin resistance
2. Fall in HbA1c
3. Platelet activation
4. BP variability
5. Fasting triglycerides
6. Obesity and its distribution
7. Carotid wall volume
8. Brain magnetic resonance imaging (MRI) indices of hypertensive damage
9. Diastolic function
10. Pulse wave analysis
11. Reduction in adverse cardiovascular events
12. Improvement in self assessed health status and ability to resist sleep
13. Reduction health services utilisation

Overall study start date
02/01/2006

Completion date
02/01/2009

Eligibility

Key inclusion criteria
1. Objectively confirmed obstructive sleep apnoea on respiratory polysomnography, with a >4% arterial oxygen desaturation index of >7.5/hour
2. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
400

Key exclusion criteria
1. Sleep apnoea symptoms of sufficient severity that CPAP is mandated by current trial evidence, such that randomisation to a control would be unethical (this decision is in the hands of the randomising physician as the equipoise point varies between units, but guidance on this is presented later)
2. Ventilatory failure (awake resting arterial oxygen saturation <93% or arterial pCO2 >6kPa)
3. Clinic BP more than 180/110
4. Cheyne-Stokes breathing on respiratory polysomnography
5. Current Heavy Goods Vehicle or Public Service Vehicle driving licence holder
6. Any sleep related accident
7. Age <45 or >75 years at trial entry (age range selected as it is typical for patients with OSA and will have a significant cardiovascular event rate)
8. Previous exposure to CPAP or non-invasive ventilation
9. Mental or physical disability precluding informed consent or compliance with the protocol for the duration of the study
10. Non-feasible trial follow-up (for example, distance from follow-up centre, physical inability)
11. Any co-incidental illness making survival for two years unlikely

Date of first enrolment
02/01/2006

Date of final enrolment
02/01/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Churchill Hospital
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
Oxford Radcliffe Hospitals NHS Trust (UK)

Sponsor details
Research and Development Department
Manor House
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
United Kingdom
OX3 9DZ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (UK) - PG/05/068

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	01/12/2012		Yes	No
Results article	results	01/09/2013		Yes	No
Results article	substudy results	01/09/2013		Yes	No
Results article	results	01/10/2014		Yes	No
Results article	results	01/02/2015		Yes	No
Results article	results	15/09/2015		Yes	No
Results article	results	16/03/2016		Yes	No