ISRCTN17987510 https://doi.org/10.1186/ISRCTN17987510

Supplemental oxygen in OSA following CPAP withdrawal

Submission date 18/02/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/02/2015	**Overall study status** Completed	
Last Edited 17/05/2021	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Obstructive sleep apnoea syndrome (OSAS) is a sleep-related breathing problem. In OSAS the back of the throat collapses during sleep, causing pauses in breathing (an apnoea), falls in oxygen levels and waking the patient from sleep many times an hour (an arousal). Because of this patients are not only sleepy during the daytime but also have higher daytime blood pressures. This puts them at risk of heart attacks and strokes. Currently the best treatment for OSAS is continuous positive airways pressure (CPAP). This is a breathing mask worn at night, blowing air onto the back of the throat at night and holding it open. This stops the throat from collapsing, stops falls in oxygen levels and stops large changes in pressure swings in the chest seen with an apnoea. CPAP treatment is effective in making patients less sleepy during the daytime and in improves daytime blood pressure. It is not known whether it is the falls in oxygen levels, the arousal or the pressure changes that cause the rise in daytime blood pressure. Oxygen treatment is given long term to patients with other chronic lung diseases safely like chronic obstructive pulmonary disease (COPD). By giving patients oxygen overnight instead of CPAP we aim to study the effect of stopping oxygen levels falling (intermittent hypoxia) on blood pressure, without affecting apnoeas or arousals. In this study we will look at the effect of giving oxygen overnight to OSAS patients previously treated with CPAP.

Who can participate?
Adults aged between 20-75 with obstructive sleep apnoea treated with CPAP for at least a year.

What does the study involve?
Patients are randomly allocated into one of two groups. Those in group 1 are given the treatment (oxygen) overnight instead of their normal CPAP for 14 days. Those in group 2 are given a placebo (air) overnight instead of their usual CPAP for 14 days. The patients are then crossed-over so that those receiving oxygen are now given the placebo treatment and vice versa.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Churchill Hospital, UKCRC Oxford Respiratory Trials Unit (UK)

When is the study starting and how long is it expected to run for?
February 2015 to June 2017

Who is funding the study?
1. Oxford Radcliffe Hospitals Charitable Fund (UK)
2. ResMed (UK)

Who is the main contact?
Miss Magda Laskawiec-Szkonter

Contact information

Type(s)
Public

Contact name
Miss Magda Laskawiec-Szkonter

Contact details
Churchill Hospital
UKCRC Oxford Respiratory Trials Unit
Oxford Centre for Respiratory Medicine
Churchill Hospital
Old Road
Oxford
United Kingdom
OX3 7LE

Type(s)
Scientific

Contact name
Prof John Stradling

ORCID ID
https://orcid.org/0000-0003-4971-5018

Contact details
Churchill Hospital
UKCRC Oxford Respiratory Trials Unit
Oxford Centre for Respiratory Medicine
Churchill Hospital
Old Road
Oxford
United Kingdom
OX3 7LE

Type(s)
Scientific

Contact name
Dr Christopher Turnbull

ORCID ID
https://orcid.org/0000-0001-8942-5424

Contact details
Churchill Hospital
UKCRC Oxford Respiratory Trials Unit
Oxford Centre for Respiratory Medicine
Churchill Hospital
Old Road
Oxford
United Kingdom
OX3 7LE

Additional identifiers

Protocol serial number
18299

Study information

Scientific Title
The effects of supplemental oxygen on obstructive sleep apnoea (OSA) and its vascular consequences during continuous positive airway pressure therapy withdrawal

Study objectives
In this study we will look at the effect of giving oxygen overnight to patients suffering from obstructive sleep apnoea syndrome (OSAS) that have previously been treated with continuous positive airways pressure (CPAP). We hypothesize that treatment of OSA patients with oxygen alone has a beneficial effect on the surrogate markers of cardiovascular risk, predominately arterial blood pressure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford B, 04/02/2015, ref: 15/SC/0007

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Not specified

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Topic: Respiratory disorders; Subtopic: Respiratory (all Subtopics); Disease: Respiratory

Interventions
Participants will be treated with oxygen or sham (air) whilst off CPAP for 14 days.
Patients are crossed-over, so that they are allocated to either CPAP withdrawal with supplemental oxygen, if they had previously received sham (air) and CPAP withdrawal with sham (air), if they had previously received supplemental oxygen after Visit 3

Intervention Type
Device

Primary outcome(s)
Home blood pressure change over 14 days; Timepoint: Home blood pressure measured every morning by the patient

Key secondary outcome(s)
1. Home heart rate change over 14 days; Timepoint; home heart rate measured every morning by the patient
2. Change in OSA severity: Timepoint: home sleep study measured before study visits 1, 2, 3, and 4
3. Change in subjective (questionnaire ESS) and objective sleepiness (OSLER test); Timepoint: ESS and OSLER measured at study visits 1,2 3, and 4
4. Change in overnight urinary catecholamine secretion; Timepoint: Overnight urine collection for catecholamines prior to visits 1, 2, 3, and 4
5. Change in gene expression (mRNA and microRNA); Timepoint; Bloods samples at visits 1, 2, 3, and 4

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Objectively confirmed obstructive sleep apnoea (at the time of original diagnosis) with an oxygen desaturation index (ODI, =4% dips) of >20/h or/and an apnoea/ hypopnoea index of >20 /h (this threshold will exclude subjects with borderline OSA, in whom there may be little treatment effect).
2. Currently >20/h oxygen desaturations (=4% dips) returning on any night during an ambulatory nocturnal pulse oximetry performed during a 4-night period without CPAP.
3. Treated with CPAP for more than 12 months, minimum compliance 4h per night, AHI <10 with treatment (according to machine download data) and ODI<10 confirmed on CPAP during screening oximetry.
4. Written informed consent
5. Upper Age Limit 75 years, lower Age Limit 20 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
25

Key exclusion criteria
1. Previous ventilatory failure (awake resting arterial oxygen saturation <93% or arterial PCO2 > 6kPa) or severe respiratory disorders other than OSA
2. Unstable, untreated coronary or peripheral artery disease, severe arterial hypertension (>180 /110mmHg), severe arterial hypotension (<90/60mmHg).
3. Previously diagnosed with CheyneStokes breathing.
4. Current professional driver.
5. Any sleep related accident.
6. Age <20 or >75 years at trial entry.
7. Severe nasal congestion.
8. Mental or physical disability precluding informed consent or compliance with the protocol
9. Nonfeasible trial followup (for example, distance from follow-up centre, physical inability).
10. Current smoker

Date of first enrolment
02/03/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Churchill Hospital
UKCRC Oxford Respiratory Trials Unit
Oxford Centre for Respiratory Medicine
Churchill Hospital Old Road
Oxford
United Kingdom
OX3 7LE

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Oxford Radcliffe Hospitals Charitable Fund (UK)

Funder Name
ResMed (UK)

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	15/01/2019		Yes	No
Results article		01/05/2021	17/05/2021	Yes	No
HRA research summary			28/06/2023	No	No