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Continuous positive airway pressure (CPAP) in patients with impaired vision due to diabetic Retinopathy and concurrent Obstructive Sleep Apnoea (OSA): ROSA trial

Submission date
17/05/2012

Recruitment status
No longer recruiting

Registration date
28/05/2012

Overall study status
Completed

Last Edited
01/10/2020

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 (OSA) is a common disorder of breathing during sleep. In this condition there are frequent but brief episodes of obstruction to the upper airway. This causes episodes where breathing slows or stops, followed by a fall in the bodys oxygen level, rise in blood pressure, and a slight wakening of the person. This can happen hundreds of times a night. The most common symptom from OSA is tiredness during the day due to poor quality sleep, but many people have no symptoms. Patients with OSA are treated with continuous positive airway pressure (CPAP) at night to prevent airway obstruction, which stops the change to oxygen levels, blood pressure, and sleep disturbance. OSA is more common in people with type 2 diabetes compared to non-diabetics, and those people with type 2 diabetes and OSA are more likely to have worse diabetic eye disease. It is currently not clear why this is. In a recent small study where CPAP was used in these people in addition to standard treatment from their eye hospitals, there was an improvement in eye sight after six months treatment, if they had used the CPAP regularly. This larger study aims to establish whether giving CPAP treatment to adults with obstructive sleep apnoea, type 2 diabetes, and established diabetic retinopathy, really can improve their vision.

Who can participate?
Patients with type 2 diabetes and related retinopathy

What does the study involve?
Before being entered into the study, consenting patients are screened for obstructive sleep apnoea by having a simple overnight sleep study done at their home. Patients suitable for the study then meet the study team. The study lasts for 12 months. During this time patients are seen 4 or 5 times. At each visit visual acuity (clarity or clearness of vision) is measured, retinal images are taken, quality of life questionnaires are completed, and blood tests are performed. Each visit is likely to take about an hour. After the initial visit, patients are randomly allocated into one of two groups. Group A are provided with CPAP therapy for a year in addition to the

existing medical treatment. Group B receive no CPAP therapy and no change to the current medical treatment.

What are the possible benefits and risks of participating?
This study is being performed to investigate whether CPAP treatment in this setting is beneficial or not. Currently the answer to this is not known. Worldwide, thousands of people use CPAP for the treatment of OSA. It is a very well tolerated treatment without any serious side effects. Minor problems with this include nasal congestion, or discomfort from a poorly fitted mask.

Where is the study run from?
The study is being co-ordinated from the Newcastle upon Tyne Hospitals NHS Foundation Trust, but involves patients being seen in the Eye Hospital they are already known to.

When is study starting and how long is it expected to run for?
August 2012 to January 2017

Who is funding the study?
The ResMed Foundation (USA)

Who are the main contacts?
1. Dr Benjamin Prudon
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2. Dr Sophie West, Respiratory Consultant
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

0.6

Study information

Scientific Title
A randomised controlled trial of continuous positive airway pressure (CPAP) in patients with impaired vision due to diabetic Retinopathy and concurrent Obstructive Sleep Apnoea (OSA): ROSA trial

Acronym
ROSA

Study objectives
Diabetic individuals are significantly more likely to have obstructive sleep apnoea (OSA) compared to the background population, independent of their body mass index (BMI). Individuals with diabetes and OSA are also more likely to develop severe diabetic retinopathy. Untreated OSA is associated with frequent surges in blood pressure and dips in arterial oxygenation during sleep, which may be a significant uncontrolled factor involved in the progression of diabetic retinopathy. A small initial trial treating these patients with continuous positive airway pressure (CPAP) improved vision at 6 months. This randomised controlled trial (RCT) aims to investigate whether CPAP treatment in individuals with diabetic retinopathy and concurrent OSA does improve vision.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre randomised controlled 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Obstructive sleep apnoea and visual impairment due to diabetic retinopathy

Interventions
Patients randomised to receive continuous positive airway pressure (CPAP) treatment with standard ophthalmology care, or only standard ophthalmology care.

Intervention Type
Procedure/Surgery

Primary outcome measure
Best corrected visual acuity (BCVA) with the study eye at 12 months (LogMAR with refraction, 4 metre Early Treatment of Diabetic Retinopathy Study protocol [ETDRS])

Secondary outcome measures
1. Best corrected visual acuity (BCVA) with the study eye at 6 months (LogMAR with refraction, 4 metre ETDRS)
2. Optical coherence tomography (OCT) central macular thickness in the study eye at 12 months (central 1mm average of radial line scans)
3. Number of ocular interventions for the study eye over 12 months (such as laser photocoagulation or intraocular injections of anti-VEGF)
4. Progression of diabetic retinopathy in the study eye at 12 months (assessed through retinal photography)
5. CPAP usage (hours/night)

Overall study start date
01/08/2012

Completion date
31/01/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 08/02/2013:
1. Type II diabetes mellitus (diagnosed on standard criteria), on diet, exercise and/or drug/insulin treatment
2. Visual impairment in at least one eye due to diabetes
3. Best corrected visual acuity (BCVA) ≥ 39 and ≤ 78 letters in at least one eye (using Early Treatment Diabetic Retinopathy Study protocol (ETDRS) at a testing distance of 4 meters)
4. Residual vision in one or both eyes
5. Macular oedema in the visually impaired eye(s)
6. 4% ODI ≥ 20/hour on the screening study
7. Aged ≥30 to ≤85
8. Patient willing to have nasal CPAP treatment

Previous inclusion criteria until 08/02/2013:
1. Type II diabetes mellitus (diagnosed on standard criteria), on diet, exercise and/or drug/insulin treatment
2. Visual impairment in at least one eye due to diabetes
3. Best corrected visual acuity (BCVA) ≥ 39 and ≤ 78 letters in at least one eye (using Early Treatment Diabetic Retinopathy Study protocol (ETDRS) at a testing distance of 4 meters)
4. Residual vision in one or both eyes

5. Macular oedema in the visually impaired eye(s)
6. Diagnosis of macular oedema within last 5 years
7. 4% ODI ≥ 20/hour on the screening study
8. Aged ≥30 to ≤85
9. Patient willing to have nasal CPAP treatment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150 patients will be randomised into the trial, to achieve this it is estimated 600 patients will need to be screened

Total final enrolment
131

Key exclusion criteria
1. Type 1 diabetes mellitus
2. Previous treatment with CPAP or non-invasive ventilation for OSA
3. Any severe complication of OSA syndrome requiring CPAP
4. Substantial problems with sleepiness, for example while driving
5. Respiratory failure (awake resting arterial oxygen saturation <93%)
6. Cataract affecting vision such that fundal assessment at baseline on slit lamp/photography is inadequate
7. Previous ophthalmological intervention rendering visual improvement in at least one eye very unlikely, as assessed by recruiting ophthalmologist
8. Mental or physical disability precluding informed consent or compliance with the protocol for the duration of the study

Date of first enrolment
23/10/2012

Date of final enrolment
31/01/2016

Locations

Countries of recruitment
England

Northern Ireland

United Kingdom

Study participating centre
Freeman Hospital
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Royal Victoria Infirmary
Dept of Ophthalmology
Newcastle
United Kingdom
NE1 4LP

Study participating centre
Sunderland Eye Infirmary
United Kingdom
SR2 9HP

Study participating centre
St James's University Hospital
Dept of Ophthalmology
Leeds
United Kingdom
LS9 7TF

Study participating centre
Bradford Royal Infirmary
Dept of Ophthalmology
United Kingdom
BD9 6RJ

Study participating centre
Bristol Eye Hospital
Retinal Research Unit
United Kingdom
BS1 2LX

Study participating centre

Royal Derby Hospital
Dept of Ophthalmology
United Kingdom
DE22 3DT

Study participating centre
Heartlands Hospital
Medical Innovation Development Research Unit
Birmingham
United Kingdom
B9 5SS

Study participating centre
The Royal Bournemouth Hospital
Dept of Ophthalmology
United Kingdom
BH7 7DW

Study participating centre
Blackpool Victoria Hospital
Clinical Research Centre
United Kingdom
FY3 8NR

Study participating centre
University Hospital of North Durham & Darlington Memorial Hospital
Dept of Ophthalmology
United Kingdom
DL3 6HX

Study participating centre
The James Cook University Hospital, Middlesbrough
Dept of Ophthalmology
United Kingdom
TS4 3BW

Study participating centre

Manchester Royal Eye Hospital
United Kingdom
M13 9WL

Study participating centre
Hospital of St Cross Rugby & University Hospital Coventry
Dept of Ophthalmology
United Kingdom
CV22 5PX

Study participating centre
University Hospital Southampton
Dept of Ophthalmology
United Kingdom
SO16 6YD

Study participating centre
Royal Shrewsbury Hospital
Dept of Ophthalmology
United Kingdom
SY3 8XQ

Study participating centre
Pinderfields Hospital
Dept of Ophthalmology
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Musgrove Park Hospital
Respiratory & Ophthalmology
Taunton
United Kingdom
TA1 5DA

Study participating centre
University Hospital of North Staffordshire
Respiratory & Ophthalmology

Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
Derriford Hospital (Royal Eye Infirmary)
Respiratory & Ophthalmology
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Belfast Health and Social Care Trust
Respiratory & Ophthalmology
United Kingdom
BT12 6BA

Study participating centre
Huddersfield Royal Infirmary
Dept of Ophthalmology
United Kingdom
HD3 3EA

Study participating centre
King's College Hospital
Respiratory & Ophthalmology
London
United Kingdom
SE5 9RS

Study participating centre
Royal Hallamshire Hospital
Respiratory & Ophthalmology
Sheffield
United Kingdom
S10 2JF

Sponsor information

Organisation
Newcastle upon Tyne NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
ResMed Foundation

Alternative Name(s)
The ResMed Foundation, Resmed Foundation Ltd, Resmed Foundation Limited

Funding Body Type
Private sector organisation

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

Location
United States of America

Results and Publications

Publication and dissemination plan

Submit data to American Thoracic Society by November 2017 for dissemination at ATS conference May 2018. Planned publication in a high-impact peer reviewed journal. Intention to publish date - early 2018.

Intention to publish date
31/01/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/10/2018	01/10/2020	Yes	No