

Obstructive Sleep Apnoea (OSA) in patients with type 2 diabetes and the effect of continuous positive airway pressure (CPAP) treatment on diabetic control, insulin resistance and blood pressure

Submission date 05/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/02/2010	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

04/Q1605/5

Study information

Scientific Title

Study objectives

CPAP treatment for OSA in men with type 2 diabetes improves insulin resistance, glycaemic control and blood pressure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

OSA and coexisting Type 2 diabetes

Interventions

CPAP and Sham (placebo) CPAP

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

HbA1c% change

Secondary outcome measures

Insulin resistance measured by euglycaemic clamp and homeostatic model assessment, blood pressure

Overall study start date

15/06/2004

Completion date

19/12/2005

Eligibility

Key inclusion criteria

1. Age 18-75
2. Type 2 diabetes
3. OSA with more than 10 >4% SaO2 dips per hour on sleep study
4. Epworth Sleepiness Score >9

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Male

Target number of participants

40

Key exclusion criteria

1. Unstable diabetes
2. Respiratory failure requiring urgent nocturnal ventilation

Date of first enrolment

15/06/2004

Date of final enrolment

19/12/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Oxford Centre for Respiratory Medicine

Oxford

United Kingdom

OX3 7LJ

Sponsor information

Organisation

Diabetes UK

Sponsor details

10 Parkway

London

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NW1 7AA

+44 (0)207 4241000

info@diabetes.org.uk

Sponsor type

Charity

Website

<http://www.diabetes.org.uk>

ROR

<https://ror.org/050rgn017>

Funder(s)

Funder type

Charity

Funder Name

Diabetes UK BDA:RD04/0002766 (UK)

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	01/11/2007		Yes	No