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Glucose monitoring in patients with obstructive sleep apnoea

Submission date
17/01/2022

Recruitment status
Stopped

Registration date
10/02/2022

Overall study status
Stopped

Last Edited
09/11/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a long-term health problem in which uncontrolled blood sugar (glucose) levels cause serious health problems. Patients with “prediabetes” have slightly raised blood sugar levels and are at risk of developing T2DM. Up to half of patients with T2DM and “prediabetes” have obstructive sleep apnoea (OSA). OSA is a breathing condition that causes loud snoring and pauses in breathing during sleep. Patients with OSA are often sleepy in the daytime, have reduced quality of life, and are at risk of road traffic collisions. Patients with OSA and T2DM or “prediabetes” have worse blood sugar control. It is not known whether OSA causes this worse blood sugar control in T2DM and “prediabetes”. We surveyed over 500 patients with OSA. 95% of respondents thought that understanding if OSA worsens diabetes is important. We aim to determine the effect of treating OSA with CPAP on overnight blood sugar levels in patients who have OSA and also have T2DM or “prediabetes”.

Continuous positive airway pressure or CPAP is the main treatment for OSA. CPAP is delivered by a snug-fitting face mask, worn by patients during sleep, which connects to a bedside machine that blows air into the lungs to restore normal breathing overnight. One way of proving that OSA worsens blood glucose control in T2DM and “prediabetes” is by showing that CPAP improves blood glucose control. Previous studies looking to use CPAP to improve blood sugar control in patients with both OSA and T2DM or “prediabetes” have been inconclusive. This could be because only average blood sugar levels were assessed by measuring HbA1c, which would not detect changes in overnight sugar levels when OSA is occurring. It also could be because the amount of CPAP used by patients in these previous studies was low.

This study will evaluate the effects of CPAP withdrawal versus continued CPAP on overnight glucose levels and other measures of cardiovascular risk, OSA severity, and daytime symptoms in patients with CPAP-treated obstructive sleep apnoea and T2DM (not on insulin therapy) or “prediabetes”. This study aims to show definitively if OSA causes worse blood sugar control in T2DM and “prediabetes”. This would be an important step to understanding if treating OSA might improve the long-term health of patients with OSA who have diabetes or “prediabetes”.

Who can participate?
Adult patients with obstructive sleep apnoea and type 2 diabetes mellitus or prediabetes. To

overcome the problem of low CPAP use, the study will invite participants who are already good users of CPAP.

What does the study involve?
Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin) for the first half of the study. The first group of participants will be asked to briefly stop their CPAP and use sham CPAP instead for one week, while the other group will continue to use their CPAP as normal. In the second half of the study, for one week participants will receive the real CPAP or sham CPAP that they did not receive in the first half of the study. There will be at least a two-week period between the two halves of the study where participants will use their normal CPAP. The study team will record blood sugar levels for the week when patients are using real CPAP and when the week when sham CPAP is used.

The study will look specifically at overnight blood glucose levels by using continuous glucose monitoring (CGM). CGM can measure blood sugar levels throughout the night for up to ten nights. CGM can comfortably be worn at home and allow patients to measure blood sugar levels whilst going about their daily lives.

What are the possible benefits and risks of participating?
Stopping CPAP is not a major concern as many patients stop their CPAP for 1-2 weeks, such as when they have a cold or when they are on holiday. In a survey run by the study team, over 60% of respondents would be willing to consider briefly stopping CPAP for research purposes.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
From April 2022 to January 2024

Who is funding the study?
Dexcom (USA) and NIHR Oxford Biomedical Research Centre (UK)

Who is the main contact?
Dr Christopher Turnbull
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
298699

Protocol serial number
IRAS 298699

Study information

Scientific Title
Continuous Glucose Monitoring in OSA (GLUCOMOSA): a randomised cross-over continuous positive airway pressure withdrawal trial

Acronym
GLUCOMOSA

Study objectives
In patients with known obstructive sleep apnoea and type 2 diabetes mellitus or prediabetes, continuous positive airway pressure (CPAP) withdrawal for one week will increase overnight interstitial glucose levels, compared to continued CPAP.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending March 2022, NHS REC

Study design
Single tertiary-centre crossover randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus, prediabetes, obstructive sleep apnoea

Interventions

This is a randomised crossover trial where participants will be randomised to one of the following two groups:
1. Stop their normal CPAP and use sham CPAP for one week, followed by at least a 2 week washout period, followed by a week of using CPAP as normal
2. Continue to use CPAP as normal for one week, followed by at least a 2 week washout period, followed by a week of using sham CPAP

Sham CPAP:
Sham CPAP will be delivered by setting the CPAP device to 4cms H2O and lowering the pressure further to 1cm H2O using extra blow-off holes in the mask tubing at the patient end. The machine is restrained from trying to compensate for this extra leak with a 5mm restriction introduced at the machine end of the tubing. Participants will use sham CPAP for 7 days instead of their normal CPAP.

Continued CPAP:
Continued CPAP will be delivered via an identical auto-adjusting CPAP machine.

The study team will record blood sugar levels for one week when patients are using real CPAP. The study team will record blood sugar levels on days 5-7 when the sham CPAP is used. Blood glucose levels will be recorded using continuous glucose monitoring (CGM).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome(s)
The effect of continuous positive airway pressure (CPAP) withdrawal on continuous interstitial glucose measurements (CGM) measured using a CGM sensor overnight, between 00:00 and 07:00, on 5, 6, and 7 days of CPAP withdrawal

Key secondary outcome(s))
The effect of continuous positive airway pressure (CPAP) withdrawal on continuous interstitial glucose measurements (CGM) measured using a CGM sensor for 24 h on 5, 6, and 7 days of CPAP withdrawal

Completion date
31/01/2024

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent for participation in the trial
2. Male or Female, aged ≥18 years

3. Objectively confirmed obstructive sleep apnoea (at the time of original diagnosis) with an oxygen desaturation index (ODI ≥4% dips) of >20 /h, and/or an apnoea/hypopnoea index of >20 /h (this threshold will exclude subjects with borderline OSA, in whom there may be little treatment effect)
4. Type 2 diabetes mellitus or HbA1c ≥6.0% (42 mmol/l) at the screening visit.
5. In the Investigator's opinion, is able and willing to comply with all trial requirements
6. Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the trial
7. Currently >20 /h oxygen desaturations (≥4% dips) returning on any night during a screening period of ambulatory nocturnal pulse oximetry performed during a 4-night period without CPAP
8. Treated with CPAP for >3 months, minimum compliance 6 h per night, where available an AHI <10 with treatment (according to machine download data), and ODI <10 confirmed on CPAP during screening oximetry

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Diabetes mellitus requiring treatment with regular insulin therapy
2. Previous ventilatory failure (awake resting arterial oxygen saturation <93% or known arterial PCO2 >6 kPa) or severe respiratory disorders other than OSA
3. Unstable, untreated coronary or peripheral artery disease, severe arterial hypertension (>180 /110 mmHg), severe arterial hypotension (<90/60 mmHg)
4. Poorly controlled diabetes with HbA1c ≥10.0% (86 mmol/mol)
5. Unstable diabetic retinopathy requiring or currently undergoing specialist treatment
6. Previously diagnosed with Cheyne-Stokes breathing
7. Current professional driver or vigilance critical occupation
8. Any sleep-related accident
9. Mental or physical disability precluding informed consent or compliance with the protocol
10. Non-feasible trial follow-up (for example the distance from follow-up centre, or physical inability)

Date of first enrolment
01/04/2022

Date of final enrolment

01/01/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford University Hospitals
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
Dexcom

Alternative Name(s)
Dexcom, Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxfordBRC, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Anonymised data will be available for sharing upon request to christopher.turnbull@ouh.nhs.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 0.3	29/03/2021	18/01/2022	No	Yes
Protocol file	version 0.5	23/04/2021	18/01/2022	No	No