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Endobarrier in diabetes with obstructive sleep ap

Submission date
04/05/2016

Recruitment status
No longer recruiting

Registration date
22/06/2016

Overall study status
Completed

Last Edited
10/07/2023

Condition category
Respiratory

[_] 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 common condition in which the upper airways (wind pipe) collapse repeatedly during sleep, blocking the flow of air into the lungs. It is characterized by repetitive pauses in breathing during sleep, despite the effort to breathe, and is associated with a reduction in the amount of oxygen in the blood (oxygen saturation). With OSA are at risk of heart disease, high blood pressure, stroke, depression and premature death. OSA is usually treated using a continuous positive airway pressure (CPAP) machine. This involves the patient wearing a face mask during sleep which is connected to the machine which supplies a constant steam of air to help keep the airways open. This improves the symptoms and hopefully the long term outlook, but it is an uncomfortable solution. OSA is associated with obesity and weight loss can improve or even cure it. Treatment with Endobarrier (placement of a thin flexible tube that is placed inside your intestine creating a physical barrier between the intestinal wall and the food so less can be absorbed) can be associated with significant weight loss and can improve blood sugar control in patients with type 2 diabetes related to their weight (diabesity). This study aims to find out if Endobarrier treatment can improve OSA in patients with diabesity to the extent that some patients no longer require their CPAP machine treatment.

Who can participate?
Obese adults with type 2 diabetes and moderate OSA which is being treated with CPAP.

What does the study involve?
Once the participant has made a decision to take part in the study, they will be invited for signing a consent form and screening checks which will include medical history, examination, blood tests (approximately 10 ml) and sleep studies (at home without CPAP) on two occasions within one week to determine whether they are eligible for the study. If they fulfil all the criteria and once recruited into the study, they will be assessed for placement of Endobarrier by gastroenterologists (tummy doctors) followed by its insertion in City Hospital as a daycase procedure. There may be individual or group information sessions including the use of models and videos to describe insertion and removal of Endobarrier devices. Potential participants will be offered the opportunity to ask questions. There will be trial assessment visits for every 3 months until one year after the insertion of Endobarrier and then for every 3 months up to one year following its removal. During these visits, participants are assessed clinically and have blood tests (approximately 10 ml taken in a fasted state), sleep studies and quality of life questionnaires. Endobarrier will be removed after 1 year, again, as a day case procedure.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
City Hospital, Birmingham (UK)

When is the study starting and how long is it expected to run for?
July 2015 to July 2019

Who is funding the study?
Diabetes Care Trust (ABCD) Limited (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
2016-001920-78

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20288

Study information

Scientific Title
In type 2 diabetes patients with obesity and obstructive sleep apnoea (OSA) who are on CPAP (continuous positive airway pressure) machine, will treatment with endobarrier lead to an improvement sleep apnoea that some no longer need treatment with overnight CPAP?

Study objectives
The aim of this study is to assess whether Endobarrier treatment in patients with diabesity and OSA treated with CPAP improves the OSA to the extent that some patients no longer require their CPAP machine treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands – Leicester Central Research Ethics Committee, Nottingham, 06/10/2015, ref: 15 /EM/0399

Study design
Non-randomised; Interventional; Design type: Treatment, Screening, Device

Primary study design
Interventional

Secondary study design
Non randomised study

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
Specialty: Diabetes, Primary sub-specialty: Both; UKCRC code/ Disease: Metabolic/ Diabetes mellitus, Respiratory/ Other diseases of the respiratory system

Interventions
During screening visit, a brief history, examination, blood tests and 2 sleep studies within a gap of 1 week will be performed. Then, there will be an assessment by gastroenterologist for endobarrier insertion. Endobarrier will be inserted endoscopically as a daycase procedure after the midnight fast, under general anaesthesia. Following the endobarrier insertion, there will be 3 monthly trial visits until one year where the following assessments will be performed – brief interview, observations, blood tests, urine test, dietitician review, compliance check with CPAP and quality of life questionnaire.

At the end of one year, endobarrier will be removed endoscopically again as a day case procedure under general anaesthesia. Then, there will be follow up trial visits every 3 months up to one year where there will be clinical assessments, sleep studies, blood tests, urine test , dietitian, compliance check and quality of life questionnaires.

Intervention Type
Other

Primary outcome measure
Requirement for continuous positive airway pressure (CPAP) treatment which will be assessed by sleep studies at screening visit and at months 3,6,9,12,15,18,21 and 24.CPAP(continuous positive airway pressure) treatment which will be assessed by sleep studies at screening visit and at months 3, 6, 9, 12, 15, 18, 21 and 24.

Secondary outcome measures
1. Apnoea hyperapnia index (AHI) is measured by sleep studies at screening, 3, 6, 9, 12, 15, 18, 21 and 24 months
2. Obstructive sleep aponea (OSA) symptoms are measured by sleep studies at screening, 3, 6, 9, 12, 15, 18, 21 and 24 months
3. Continuous positive airway pressure (CPAP) pressures are measured by sleep studies at screening, 3, 6, 9, 12, 15, 18, 21 and 24 months
4. Glycated haemoglobinis measured by blood test (HbA1c) at screening, baseline, 3, 6, 9, 12, 15, 18, 21 and 24 months
5. Fasting plasma glucose is measured by blood test(fasting plasma glucose) at baseline, 12 and 24 months
6. Weight and Body mass index (BMI) is measured by checking weight as well as height at screening, baseline, 3, 6, 9, 12, 15, 18, 21 and 24 months
7. Composite scores of NAFLD severity derived from age, Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), BMI, platelets and serum albumin are measured by blood tests (ALT, AST, platelets, albumin), age and observations (weight, height) at screening, baseline, 3, 6, 9, 12, 15, 18, 21 and 24 months
8. Circulating free testosterone, fasting insulin and C-Peptide are measured by blood tests at baseline, 3, 12 and 24 months
9. Blood pressure is measured by checking blood pressure at sitting at screening, baseline, 3, 6, 9, 12, 15, 18, 21 and 24 months
10. Diabetes treatment including need for insulin is measured at baseline, 3, 6, 9, 12, 15, 18, 21 and 24 months
11. Quality of life scores is measured by EQ-5D questionnaire at baseline and 6, 12 and 24 months
12. Sustainability of primary outcome and of the secondary outcomes during the year following explantation of Endobarrier is measured by blood tests, sleep studies and interview at 15, 18, 21 and 24 months

Added 08/02/2017:
13. Circulating free testosterone, insulin and c-peptide level are measured using blood testing at baseline, 3, 12 and 24 months

Overall study start date
13/07/2015

Completion date
12/07/2019

Eligibility

Key inclusion criteria
Inclusion criteria as of 08/02/2017:
1. Moderate OSA
2. On CPAP
3. Type 2 diabetes or prediabetes with HbA1c between 42 and 48 mmol/mol
4. Obesity BMI ≥30 and ≤45 Kg/m2
5. Aged 18 years and over
6. Capable of giving informed consent

Original inclusion criteria:
1. Moderate OSA
2. On CPAP
3. Type 2 diabetes
4. Obesity BMI ≥30 and ≤40 Kg/m2
5. Aged 18 years and over
6. Capable of giving informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 18; UK Sample Size: 18

Total final enrolment
12

Key exclusion criteria
1. Abnormal intestinal anatomy
2. Contraindication to oesophagogastroduoenoscopy
3. Previous bariatric surgery or bowel surgery
4. Active infection
5. Anticoagulation therapy
6. Coagulopathy INR >1.3
7. Estimated Glomerular Filtration Rate (eGFR) <30
8. Known portal hypertension
9. Uncontrolled cardiovascular disease

10. Lactating or pregnant females
11. Excess anaesthetic risk
12. Patients taking non steroidal anti-inflammatory agents will need to discontinue these for the duration of Endobarrier implantation
13. Patients taking aspirin with active ischaemic heart disease or cerebrovascular disease or those in whom aspirin treatment should continue. Patients taking regular aspirin will need to discontinue it for the duration of the Endobarrier implantation and so for those in whom it is taken for primary prevention, the potential risks and benefits of deciding to discontinue aspirin will be weighed up by the clinician concerned in consultation with the patient.

Date of first enrolment
14/03/2016

Date of final enrolment
16/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
City Hospital
Sandwell and West Birmingham Hospital NHS Trust
Dudley Road
Birmingham
United Kingdom
B18 7QH

Sponsor information

Organisation
Sandwell and West Birmingham Hospitals NHS Trust

Sponsor details
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England
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05mzf3276

Funder(s)

Funder type
Charity

Funder Name
Diabetes Care Trust (ABCD) Limited

Results and Publications

Publication and dissemination plan
Study results will be published in a peer reviewed journal once the data analysis is complete.

Intention to publish date
31/08/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Abstract results		01/09/2020	10/07/2023	No	No