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Decongestants in Obstructive Sleep Apnoea (DOSA)

Submission date
08/01/2019

Recruitment status
Stopped

Registration date
17/01/2019

Overall study status
Stopped

Last Edited
25/11/2021

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Obstructive Sleep Apnoea (OSA) is a very common condition in around 1 in 20 adults. When you relax during sleep the throat tends to narrow. In OSA patients this narrowing leads to collapse and pauses in breathing. During these pauses the oxygen level falls and the patient wakes up. These events can occur every minute in severe cases and so patients sleep very badly. They wake unrefreshed and are sleepy in the daytime. OSA is best treated with a Continuous Positive Airway Pressure (CPAP) machine. These machines blow air into the throat through a mask worn when asleep. CPAP keeps the airway open. The breathing is stable and sleep is not disrupted. Patients awake refreshed and do not fall asleep in the daytime. CPAP can also help snoring, blood pressure, mood and going to the toilet too often at night. Although CPAP machines work well they are not always comfortable. Around one in 10 patients do not use CPAP very well. Patients who don't like CPAP ask if there are any other treatments or if they can stop CPAP machines for short breaks. However, no other therapy is as effective, although intra-oral devices that hold the lower jaw forward during sleep can be almost as effective in some patients. There have been studies looking at other alternatives, but these do not seem to be adequate replacements. It is known that snoring is worse if the throat is swollen or the nose is blocked. This can also lead to OSA. Snoring may be improved by nasal decongestants. The aim of this study is to find out whether these decongestants will also treat OSA so that patients can come off their CPAP for short breaks.

Who can participate?
Patients aged 18 or over with mild-moderate OSA who have already been using CPAP treatment for at least 6 months

What does the study involve?
Participants are asked to stop using the CPAP machines for a maximum of 28 days and are randomly allocated to receive either a decongestant nasal spray or a placebo (dummy) spray to spray into each nostril and either side of their throat before bed every night, until they feel their symptoms have returned or the trial team can see the return via remote monitoring. Participants are also asked to wear an overnight oximeter device every night and also complete e-diaries on a daily basis. The aim is to see how long it takes for the participant's sleep apnoea symptoms to return. If the nose spray stops OSA coming back for a week or more this will help people to

decide if they can go away for a few days without having to take their machine. This treatment is only given for a maximum of 28 days at which time the participant should re-start their CPAP treatment. If the participant feels that their symptoms have returned prior to the 28 days or the researchers see they have from the remote monitoring system, they are contacted to restart their CPAP treatment. Two visits to the local sleep centre are required to complete a suite of questionnaires, undergo nose and throat examinations, and answer questions about health and lifestyle.

What are the possible benefits and risks of participating?
There is no direct benefit for the participant but the study will show whether using nasal sprays in the nostrils and throat reduces the time of return of sleep apnoea symptoms. This study will hopefully result in an alternative temporary therapy for those participants wishing to have a "break" from traditional sleep apnoea treatments for things such as holidays. A potential risk of taking part is the return of day time sleepiness, at which point CPAP therapy should be recommenced. There may be some side effects from the nasal sprays.

Where is the study run from?
The Oxford Respiratory Trials unit are sponsoring and managing the trial on behalf of Taunton and Somerset NHS Foundation Trust. There will be two recruiting sites initially, Oxford and Taunton.

When is the study starting and how long is it expected to run for?
July 2018 to February 2021

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
1. Emma Hedley
2. Dr Justin Pepperell

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
2018-000065-37

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
40486; PB-PG-1216-20038

Study information

Scientific Title
Randomised controlled trial of nasal decongestants versus placebo to prolong treatment free periods from continuous positive airway pressure therapy in mild to moderate obstructive sleep apnoea

Acronym
DOSA

Study objectives
In patients with mild-to-moderate OSA currently on CPAP, pre-sleep administration of a nasal and pharyngeal decongestant will prolong the OSA-free period following CPAP-withdrawal.

Ethics approval required
Old ethics approval format

Ethics approval(s)

North East – Tyne & Wear South Research Ethics Committee, NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, +44 (0)207 1048083, 24/12/2018, ref: 18/NE/0365

Study design
Randomised; Interventional; Design type: Treatment, Drug

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

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

Interventions
The intention is to ask participants to stop using their CPAP treatment and during visit 1 will be randomised to either a real nasal spray or placebo. Participants will also be asked to wear an overnight oximeter every night and also complete e-diaries on a daily basis. Participants will then be advised to spray them into each nostril and either side of their throat prior to bed every night. The primary outcome of the study is to see how long it takes for the participant's sleep apnoea symptoms to return. This treatment will only be given for a maximum of 28 days at which time the participant should re-start their CPAP treatment. If the participant feels that their symptoms have returned prior to the 28 days or the trialists see they have from the remote monitoring system, the trialists will contact the participant to restart their CPAP treatment. Participants will then be asked to continue to complete their e-diary for a further 7 days post nasal sprays before attending for their final visit, visit 2.

Intervention Type
Drug

Phase
Phase II/III

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

Primary outcome measure

The number of days to return of OSA, defined as an ODI > 15 on 3 consecutive nights or 2 nights with inadequate data between, or to intolerable return of symptoms such that patient requests resumption of CPAP therapy. Measured by overnight every night pulse oximetry and by patient self-reported symptoms. Timepoint(s): 28 days

Secondary outcome measures
1. Patient-reported sleepiness, measured using Epworth sleepiness score at baseline and weekly (day 0, 7, 21 and 28) until 5-week follow-up
2. Overnight pulse rate rises as a marker of autonomic arousal during sleep fragmentation, measured by overnight every night pulse oximetry during 28 day withdrawal of CPAP

Overall study start date
01/07/2018

Completion date
01/04/2021

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the trial
2. Male or female, aged 18 years or above
3. Diagnosed with proven obstructive sleep apnoea, with an ODI > 15 and < 30 on original diagnostic sleep study
4. Established on CPAP treatment for > 6 months with mean usage of > 4 hours/night for last 6 months
5. In the Investigator’s opinion, is able and willing to comply with all trial requirements
6. Willing to withdraw from CPAP treatment for 28 days
7. Good mobile phone reception
8. Use of Wi-Fi at home

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 232; UK Sample Size: 232

Key exclusion criteria
1. Significant renal or hepatic impairment
2. Scheduled elective surgery or other procedures requiring general anaesthesia during the trial
3. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participant at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial
4. Participants who have participated in another research trial involving an investigational product in the past 12 weeks
5. Professional driver or, as assessed by the local investigator, any other vigilance critical activity
6. Daytime SaO2 < 93%, arterial blood gas showing PaO2 < 8.0 kPa or PaCO2 > 6.0, significant hypoventilation on diagnostic sleep study mean saturation < 92%
7. Previous or current history of central sleep apnoea or Cheyne-Stokes respiration
8. Previous history of a sleepiness-related accident
9. Female participant who is pregnant, lactating or planning pregnancy during the course of the trial
10. Participants with a fructose intolerance

Date of first enrolment
01/02/2019

Date of final enrolment
01/02/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Taunton and Somerset NHS Foundation Trust
United Kingdom
TA1 5DA

Study participating centre
Oxford Respiratory Trials Unit
Churchill Hospital
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Sponsor information

Organisation
University of Oxford

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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1216-20038

Results and Publications

Publication and dissemination plan
The CI shall submit once a year throughout the clinical trial, or on request, an Annual Progress Report to the REC, host organisation and Sponsor. In addition, an End of Trial notification and final report will be submitted to the MHRA, the NIHR, host organisation and Sponsor.

The investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by NIHR. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

Intention to publish date
30/04/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a repository.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No