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Improved olfaction under continuous positive airway pressure therapy

Submission date
04/10/2016

Recruitment status
No longer recruiting

Registration date
12/10/2016

Overall study status
Completed

Last Edited
08/11/2023

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] 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 condition in which the upper airways (wind pipe) collapse repeatedly during sleep, stopping the flow of air into the lungs. This prevents the sufferer from being able to breathe properly while they are asleep, causing excessive sleepiness throughout their waking hours. 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. Although this therapy has been using for decades now, it is not known whether it affects a patient's sense of smell. This study consists of two parts, in the first part the aim of this study is to find out whether sense of smell changes as a result of undergoing CPAP as part of standard care. In the second part, participants receiving CPAP are randomly allocated to continue with treatment or have the pressure of the device lowered (so it is no longer as effective) in order to see if this impacts on sense of smell.

Who can participate?
Adults with moderate to severe OSA who suffer from daytime sleepiness

What does the study involve?
In the first part of the study participants attend a study visit at which they complete a questionnaire about their sleepiness and sense of smell. Their sense of smell is then tested by asking participants to smell a number of scent dispensing smells. Following this, participants begin standard CPAP therapy as part of their usual care. Three months later, participants attend a second study visit at which time the questionnaires and smell tests are repeated in order to find out if CPAP has had an effect on their sense of smell and how tired they are during the day. In the second part of the study, participants able to stick to the CPAP therapy in the first part of the study are randomly allocated to one of two groups. Those in the first group continue with their standard CPAP therapy for three weeks, those in the second group have the pressure of the CPAP device lowered for three week so it is no longer working as well. At the start of this treatment period and then after three weeks, participants complete questionnaires and smell tests in order to assess their sense of smell and how tired they are during the day.

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

Where is the study run from?
Cantonal Hospital Aarau (Switzerland)

When is the study starting and how long is it expected to run for?
February 2014 to August 2016

Who is funding the study?
Research Council of the Cantonal Hospital Aarau (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
EKNZ 2014-335

Study information

Scientific Title
Significant improvement of olfactory performance in sleep apnea patients after three months of nasal continuous positive airway pressure therapy

Study objectives
The aim of this study is to assess the sense of smell before initiation of nasal continuous positive airway pressure (CPAP) and after three months treatment, in moderate and severe obstructive sleep apnea (OSA) patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Nordwest- und Zentralschweiz, 18/11/2014, ref: EKNZ 2014-335
Amendment approved: 19/05/2016

Study design
Part 1: Observational cohort study; Part 2: Randomized controlled trial

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Olfactory performance in moderate and severe sleep apnea patients

Interventions
Part 1:
Participants attend a study visit at which they undergo several investigations. Firstly, a questionnaire concerning sleepiness and self-estimated quality of the own olfaction has to be answered which takes about five minutes. Secondly, sense of smell is tested with the aid of a standardized test battery. This test battery contains 112 odour-dispensing pens to evaluate odour threshold, odour discrimination and odour identification. These pens are exposed to the nose of the patient in a specific order. The test takes about 40 minutes.
During the same visit patients then begin standard CPAP therapy as part of their usual care. This involves adaptation of a suitable nasal mask and instruction of the patient how to use and to maintain the CPAP device and the humidifier.

After three months, participants attend another study visit at which they undergo the same procedure of testing the sense of smell and answering the same questionnaire as during the initial study visit. Furthermore, after these tests a download of the therapy data are discussed with the patient and a check of the CPAP device is performed. This follow up visit takes about 90 minutes.

Part 2:
Participants who show a sufficient therapy adherence during the first follow up visit are randomized to one of two groups using block randomization if they agree to take part to the second study part and give written informed consent. Sufficient therapy adherence is defined as applying the CPAP therapy in 70% of the nights at least 4 hours CPAP use per night.

Group 1: Patients maintain under unchanged CPAP therapy for three weeks (maintenance group)
Group 2: Therapy pressure of the CPAP device is set to a sub therapeutic pressure of 4 centimeter of water for three weeks (sham group).

Follow up for all participants involves testing of sense of smell and answering the study questionnaire much like they did at the follow up visit. The visits take place at the outpatients department of the Cantonal Hospital Aarau, Switzerland.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
Part 1:
Self-estimated olfaction is measured using a visual analogue scale (VAS) at baseline and 3 months.

Part 2:
Self-estimated olfaction is measured using a visual analogue scale (VAS) at baseline and 3 weeks.

Key secondary outcome(s))
Part 1:
1. Odor threshold, odor discrimination, odor identification and the summarized value of these three tests threshold, discrimination and identification overall score (TDI) are measured with the aid of a standardized test battery (sniffin'sticks) at baseline and 3 months
2. Daytime sleepiness is measured using the Epworth sleepiness scale (ESS) at baseline and 3 months

Part 2:
1. Odor threshold, odor discrimination, odor identification and the summarized value of these three tests threshold, discrimination and identification overall score (TDI) are measured with the aid of a standardized test battery (sniffin'sticks) at baseline and 3 weeks
2. Daytime sleepiness is measured using the Epworth sleepiness scale (ESS) at baseline and 3 weeks

Completion date
16/08/2016

Eligibility

Key inclusion criteria
1. Outpatients of our department of pulmonary and sleep medicine
2. Age 18 years and over
3. Suffer from daytime sleepiness
4. Show moderate to severe OSA (apnea hypopnea index (AHI) ≥ 15 per hour) in a respiratory sleep study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
35

Key exclusion criteria
1. Lack of written informed consent
2. Insufficient knowledge of the German language
3. Known disease of the nasal cavity or sinuses, or topical nasal therapy usage

Date of first enrolment
19/11/2014

Date of final enrolment
15/07/2015

Locations

Countries of recruitment
Switzerland

Study participating centre
Cantonal Hospital Aarau
Clinic of Pulmonary and Sleep Medicine
Tellstrasse 25
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Sponsor information

Organisation
Cantonal Hospital Aarau

ROR
https://ror.org/056tb3809

Funder(s)

Funder type
Research council

Funder Name
Research Council of the Cantonal Hospital Aarau

Results and Publications

Individual participant data (IPD) sharing plan
The participant level data will not be made available at the request of the approving ethics committee.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/02/2017		Yes	No
Basic results		10/10/2016	13/10/2016	No	No
Protocol (other)		03/02/2017	08/11/2023	No	No