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Comparison of two methods to treat obesity hypoventilation syndrome: Noninvasive ventilation (NIV) and continuous positive airway pressure (CPAP)

Submission date
16/02/2017

Recruitment status
No longer recruiting

Registration date
27/02/2017

Overall study status
Completed

Last Edited
26/11/2020

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Obesity is a worldwide public health issue. The main respiratory (breathing) complication caused by obesity is called obesity hypoventilation syndrome (OHS). OHS causes difficulty breathing both during the day and during sleep. OHS is an underdiagnosed and undertreated condition, despite the fact there are treatments that improve quality of life and decreases morbidity (illness) in these patients. The main treatments for patients with OHS are through providing a positive airway pressure through noninvasive ventilation (NIV). This involves the patient wearing a face mask during sleep which is connected to the machine that supplies a constant steam of pressurised air to help keep the airways open. A potential alternative treatment for patients who use NIV is a continuous positive airway pressure (CPAP) machine that is used at night. A CPAP has similarities to an NIV but provides continuous air during the night and is less expensive. The aim of this study is to test the effect of switching patients with OHS who are undergoing long term treatment with NIV, to using a CPAP and evaluate the clinical features and quality of life between these two methods of treating OHS.

Who can participate?
Adults with obesity hypoventilation syndrome

What does the study involve?
Participants undergoing treatment for OHS using NIV are switched to using a CPAP at night. This involves wearing a mask over the face or mouth that is attached to a machine that provides a continuous flow of air. Participants have night sleep recordings with a polysomnograph which is a device connected to the patient all night long to record breaks and decreases in breathing. Participants are followed up after one month of using the CPAP machine to measure their lung function and the oxygen levels in their blood. Participants also fill out a quality of life and symptoms questionnaire after one month to see if there was any change between the two different treatments.

What are the possible benefits and risks of participating?
There are no direct benefits or risks of participating.

Where is the study run from?
1. Hôpital d'instruction des armées Alphonse Laveran (France)
2. Hôpital Nord (France)

When is the study starting and how long is it expected to run for?
February 2015 to March 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Alain Palot

Contact information

Type(s)
Scientific

Contact name
Dr Alain Palot

Contact details
Hôpital NORD
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CIL/APHM 2016-26

Study information

Scientific Title
Switch of noninvasive ventilation (NIV) to continuous positive airway pressure (CPAP) in patients with obesity hypoventilation syndrome: a proof of concept study in real life conditions

Study objectives

Null Hypothesis:
There will be no difference in efficacy when switching from noninvasive ventilation (NIV) to continuous positive airway pressure (CPAP) on AHI (apnea-hypopnea index), diurnal and nocturnal alveolar gas exchange (daytime arterial blood gas (ABG), night-time transcutaneous oxygen saturation and transcutaneous measurement of pCO2), as well as no difference in sleepiness, quality of sleep and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Observational studies with no additional intervention or additional data collected do not require an ethics approval in France. The only regulatory requirement is the "CNIL" authorization for analysis of data collected.

Study design
Prospective observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Obesity hypoventilation syndrome

Interventions
Participants undergoing treatment for obesity hypoventilation syndrome (OHS) undergo a systematic pre-established switch from using non invasive ventilation (NIV) to using a continuous positive airway pressure (CPAP) at night for one month. This includes wearing a mask over the face or mouth at night that is attached to a CPAP machine that provides a positive continuous flow of air.

Sleep recordings are taken using a polysomnograph which is a device connected to the patient at night to record breathing parameters (i.e. breathing breaks called apneas and decreases in breathing amplitude called hypopneas). Participants are followed up after one month of using the CPAP machine to measure their lung function and to asses the oxygen levels in their blood. Participants also fill out a quality of life and symptoms questionnaire after one month to test the severity of their OHS, their lung function and their blood gas exchange movements.

Intervention Type

Device

Primary outcome measure
Severity of sleep apnea is measured using the Apnea-Hypopnea index at baseline and 1 month after starting of CPAP.

Secondary outcome measures
1. Oxygen saturation and transcutaneous measurement of pCO2 are measured using daytime arterial blood gas and nocturnal alveolar gas exchange at baseline and 1 month after starting of CPAP
2. Sleepiness is measured using the Epworth Sleepiness Scale (EPS) at baseline and 1 month after starting of CPAP
3. Quality of sleep is measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline and 1 month after starting of CPAP
4. Quality of life is measured using Severe Respiratory Insufficiency questionnaire (SRI) at baseline and 1 month after starting of CPAP

Overall study start date
01/02/2015

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. 18 years old or older
2. Suffering from obesity hypoventilation syndrome (OHS) defined as an association of obesity (BMI ≥ 30 kg/m²) and daytime hypercapnia (paCO2 > 45 mm Hg))
3. Patients who had been undergoing noninvasive ventilation (NIV) for more than 2 months
4. Clinically stable for at least 4 weeks before enrollment in the study (no hospitalization or emergency admission)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15

Total final enrolment
22

Key exclusion criteria
1. Hypercapnia secondary to other causes (obstructive pulmonary diseases (FEV1/FVC < 70), interstitial lung diseases, neuromuscular or chest wall diseases, severe hypothyroidism or congenital central hypoventilation syndrome)
2. Patients unable to give informed consent to data collection and analysis

Date of first enrolment
01/09/2015

Date of final enrolment
01/02/2016

Locations

Countries of recruitment
France

Study participating centre
Clinique des Bronches, Allergies et Sommeil (APHM)
Hospital Nord
Chemin des Bourrely
Marseille
France
13015

Study participating centre
Service de Pneumologie
Hôpital d'instruction des armées Alphonse Laveran
34 Boulevard Laveran
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Sponsor information

Organisation
Alain Palot

Sponsor details
Hôpital Nord
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Sponsor type
Not defined

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/03/2018

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/03/2017	26/11/2020	Yes	No