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Randomised controlled trial of average volume-assured pressure support (AVAPS) versus spontaneous/times (ST) mode pressure support ventilation in obesity hypoventilation syndrome

Submission date
15/09/2008

Recruitment status
No longer recruiting

Registration date
11/12/2008

Overall study status
Completed

Last Edited
30/11/2012

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims?
There is an increase worldwide in obesity and obesity related respiratory problems. In patients with severe obesity, significant breathing problems can develop which may prevent them from breathing properly during sleep. This can cause a build-up of waste gas in the blood and is called respiratory failure. Although this problem is increasingly common the best way to treat it remains unclear. The study was designed to evaluate a new medical device aimed at better controlling patients breathing during sleep in order to improve their breathing.

Who can participate?
Patients can participate in the study if they suffer with both severe obesity and respiratory failure without other underlying breathing or muscle problems.

What does the study involve?
The study involves being randomly picked to receive either standard treatment or the new device for a 3 month period. Patients will be unaware of which device they are given and will perform a number of tests to assess breathing and sleep as well as complete questionnaires to inform us as to how their condition affects their everyday lives.

What are the possible benefits and risks of participating?
It is not thought that there are any specific risks associated with the new device but taking part in the trial will involve additional trips to hospital. It is hoped that the new device may offer some improvements in symptom control and tolerability for patients.

Where is the study run from?
The lead study site is the Lane Fox Unit, St Thomas Hospital part of the Kings Academic Health Science Centre.

When is the study starting and how long is it expected to run for?
The study started in 2008 and was completed in 2010.

Who is funding the study?
Philips-Respironics

Who is the main contact?
Dr Patrick Murphy
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EAME2007AVAPS001

Study information

Scientific Title

Acronym
AVAPS-OHS

Study objectives

Average volume-assured pressure support (AVAPS) mode will deliver nocturnal ventilatory support more effectively than the spontaneous/times (S/T) mode and have greater physiological and clinical benefits in a subgroup of obesity hypoventilation syndrome (OHS) patients with severe obesity and marked daytime hypercapnia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Guys Research Ethics Committee, South London REC Office 3 gave approval on the 21st January 2008 (ref: 07/H0804/140)

Study design
Randomised parallel-group controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Obesity hypoventilation syndrome

Interventions
Bi-level positive airway pressure (BiPAP) ventilator will provide both the S/T and AVAPS modes.

Total duration of intervention/follow-up: 3 months

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Effectiveness of the nocturnal ventilatory support, assessed using the PaCO2 - daytime arterial blood gas (ABG) at baseline and 3 months

Secondary outcome measures

Physiological and clinical benefits in a subgroup of OHS patients with severe obesity and marked daytime hypercapnia, assessed by the following at baseline and 3 months:
1. Partial pressure of oxygen in arterial blood (PaO2), pH, bicarbonate areterial blood gas (HCO3-ABG)
2. Health related quality of life: Severe Respiratory insufficiency Questionnaire, Fatigue Severity Questionnaire
3. Anthropometric data: weight, BMI, neck, hip and waist circumference
4. Activity: Actiwatch®
5. Daytime vigilance: Epworth Sleepiness Scale, Oxford Sleep Resistance (OSLER) test

Overall study start date
01/09/2008

Completion date
01/09/2009

Eligibility

Key inclusion criteria
1. Both males and females, aged 18 - 90 years
2. Body mass index (BMI) greater than 40 kg/m^2
3. Daytime partial pressure of carbon dioxide in the arterial blood (PaCO2) greater than 6.5 kPa

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
Forced expiratory volume in one second (FEV1)/forced vital capacity (FVC) less than 70%

Date of first enrolment
01/09/2008

Date of final enrolment
01/09/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Lane Fox Respiratory Unit
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Respironics International, Inc. (France)

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Sponsor type
Industry

Website
http://www.respironics.com

ROR
https://ror.org/05jz46060

Funder(s)

Funder type
Industry

Funder Name
Respironics International, Inc. (France)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2012		Yes	No