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Domiciliary application of non-invasive positive pressure ventilation with average volume assured pressure support to subjects with chronic obstructive pulmonary disease (COPD) who remain hypercapnic following the application of non-invasive positive pressure ventilation (NPPV) for an acute exacerbation

Submission date
15/09/2008

Registration date
11/12/2008

Last Edited
11/12/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Respiratory

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
EAME06NIV01

Study information

Scientific Title

Acronym
AVAPS-COPD

Study objectives
Long-term domiciliary non-invasive positive pressure ventilation (NPPV) with average volume assured pressure support (AVAPS) in subjects with chronic obstructive pulmonary disease (COPD) who remain hypercapnic following the application of NPPV for an acute exacerbation will improve daytime partial pressure of carbon dioxide (PCO2) and endothelial dysfunction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Protection of Human Subjects, Grenoble University Hospital (CHU de Grenoble) (ref: CPP08-RESP-1), approval pending as of 11/12/2008.

Primary study design
Interventional

Study design
Randomised, parallel group pilot study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
Treatment group will receive standard optimal care plus NPPV with AVAPS support, ventilatory support function that dynamically determines the pressure support level, which generates the target or control level of exhaled tidal volume by producing a gradual pressure change based on the preceding several breaths.

Control group will receive standard optimised care.

Total duration of interventions/follow-up: 1 year

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Daytime PCO2, measured by arterial blood gases at baseline, 1, 3, 6 months and 1 year
2. Endothelial dysfunction, measured by peripheral arterial tone (PAT) at baseline, 1, 3, 6 months and 1 year

Key secondary outcome(s)
1. Lung function, measured by spirometry, according to the joint recommendations of the ERS /ATS. Timepoints of assessment: baseline, 1, 3, 6 months and 1 year
2. Dyspnoea, measured at rest by the Borg scale. Timepoints of assessment: baseline, 1, 3, 6 months and 1 year.
3. Fatigue, measured by Fatigue Severity Scale (FSS). The FSS questionnaires contains nine statements that rate the severity of the subject's fatigue symptoms an a scale from 1 to 7. A total score of less than 36 suggests that the subject may not be suffering from fatigue, while a score of greater than or equal to 36 indicates excessive fatigue. Timepoints of assessment: baseline, 1, 3, 6 months and 1 year.
4. Sleep quality, measured by polysomnography (PSG), including transcutaneous PCO2. At baseline, PSG will be performed in spontaneous breathing in order to characterise the abnormal respiratory events associated with COPD and identify obstructive sleep apnoea (OSA). Sleep and respiratory events will be recorded and scored manually according to standard criteria. REM hypoventilation will be scored when a progressive oxygen desaturation is associated with a sustained reduction in both flow and thoracic components of ventilation. During the same period, a constant or reduced respiratory drive (assessed by a reduction in respiratory effort as demonstrated by pulse transit time) should be observed without characteristic apnoeic or hypopnoeic episodes. At 3 months and 1 year, polysomnography will be done in spontaneous breathing or using non-invasive ventilation depending the arm of the study. Timepoints of assessment: baseline, 3 months and 1 year.
5. Objective sleepiness as measured by the Osler Test. This test consists of a 40 minutes sleep-resistance challenge conducted in a dark and quiet room. The subject will be asked to remain awake while reacting to a visual stimulus, which appears for 1 second every 3 seconds, by hitting a button. Sleep latency will be defined as the delay between the onset of the test and the moment corresponding to seven consecutive flashes (i.e. 21 seconds) without response. Fluctuations in vigilance and micro-sleep episodes will be quantified as the number of occasions that 3 to 6 consecutive flashes occur without response (i.e. 9 to 18 seconds without response of the patient). Timepoints of assessment: baseline, 1, 3, 6 months and 1 year.
6. Exercise capacity. At baseline a practice test will be performed at least one hour before the actual test. The highest 6-minute walk distance will be reported as the patient's 6-minute walk distance at baseline. Timepoints of assessment: baseline, 1, 3, 6 months and 1 year.
7. Physical activity. This will be objectively measured using the Actiwatch®. The Actiwatch® measures activity with a piezo-electric accelerometer that records intensity, amount and duration of movement in all directions. Timepoints of assessment: baseline, 1, 3, 6 months and 1 year.
8. Quality of life, measured using the validated French version of the St Georges Respiratory Questionnaire. Timepoints of assessment: baseline, 1, 3, 6 months and 1 year.
9. Arterial stiffness, determined by pulse wave velocity (PWV). Timepoints of assessment: baseline, 1, 3, 6 months and 1 year.
10. Time in hospital over course of follow up period

Completion date
01/11/2010

Eligibility

Key inclusion criteria
1. Both males and females, aged 50 - 80 years
2. Confirmed diagnosis of COPD according to the joint recommendations of the European Respiratory Society/American Thoracic Society (ERS/ATS)
3. Minimum of 48 hours without NPPV after using NPPV or invasive ventilation in hospital during an acute exacerbation of COPD
4. Persistent hypercapnia (partial pressure of carbon dioxide in the arterial blood [PaCO2] greater than or equal to 50 mmHg, but less than 65 mmHg with an arterial pH above 7.32) during room air spontaneous breathing
5. Able to follow instructions
6. Able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Actively smoking
2. Therapy with systemic steroids
3. Important concomitant chronic systemic diseases (i.e. chronic heart failure [left ventricular ejection fraction less than 45%], diabetes, infections, neoplasm, forms of sleep disordered breathing, etc)
4. Other chronic respiratory diseases (e.g., significant fibrothorax, bronchiectasis, cystic fibrosis)

Date of first enrolment
01/11/2008

Date of final enrolment
01/11/2010

Locations

Countries of recruitment
France

Study participating centre
Laboratoire Exploration Fonctionnelle Cardio-Respiratoire (EFCR)
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Sponsor information

Organisation
Respironics International, Inc. (France)

ROR
https://ror.org/05jz46060

Funder(s)

Funder type
Industry

Funder Name
Respironics International, Inc. (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration