

# 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

<b>Submission date</b> 15/09/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/12/2008	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 (PCO<sub>2</sub>) 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.

**Study design**

Randomised, parallel group pilot study

**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**

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 measure**

1. Daytime PCO<sub>2</sub>, 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

## **Secondary outcome measures**

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 on 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 PCO<sub>2</sub>. 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

### **Overall study start date**

01/11/2008

### **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 [PaCO<sub>2</sub>] 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

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

60

### **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)

Grenoble

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## **Sponsor information**

**Organisation**

Respironics International, Inc. (France)

**Sponsor details**

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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