

Non-invasive mechanical ventilation with average volume assured pressure support (AVAPS) in hypercapnic encephalopathy

Submission date 07/09/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 18/09/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/05/2017	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Patients with chronic obstructive pulmonary disease (COPD) have a number of lung conditions that make it difficult to breathe. NIMV (non-invasive mechanical ventilation) is a method of non-invasive ventilatory (breathing) support which deliver air through a face mask in order to keep the airways open. This is used to help patients with acute respiratory failure. One of the main problems with NIMV is that it can alter the consciousness of its users. A Bilevel positive airway pressure machine (BiPAP) such as another non-invasive form of therapy that provides continuous airway pressure to help patients breath. Bilevel positive airway pressure-spontaneous/timed (BiPAP S/T) with average volume assured pressure support (AVAPS) allows for setting a fixed tidal volume, and the system output automatically adjusts based on variations in inspiratory pressure to ensure the target value. Its long-term benefits have been demonstrated in patients with chronic respiratory failure, and other breathing issues such as obstructive sleep apnea, and alveolar hypoventilation syndrome. It could be helpful for COPD patients. The aim of this study is to determine if using a BiPAP S/T with AVAPS as the first line of noninvasive ventilatory treatment in patients with exacerbations of COPD and hypercapnic encephalopathy, is useful and safe.

Who can participate?

Adults over the age of 40 who are diagnosed with COPD or Hypercapnic encephalopathy.

What does the study involve?

Participants are randomly allocated to receiving either BiPap S/T with AVAPs or to being in the control group. Participants are followed up for their level of consciousness, how long they required the use of the ventilation, their hospital stays and their progression.

What are the possible benefits and risks of participating?

Not provided at time of registration.

Where is the study run from?

Geraneos (Ecuador)

When is the study starting and how long is it expected to run for?
February 2009 to September 2011

Who is funding the study?
Universidad San Francisco de Quito (Ecuador)

Who is the main contact?
Dr Killen Briones Claudett
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1857461069795800

Study information

Scientific Title
Non-invasive mechanical ventilation with average volume assured pressure support (AVAPS) in patients with chronic obstructive pulmonary disease and hypercapnic encephalopathy: prospective interventional match-controlled study

Study objectives
To determine if the use of BiPAP S/T with AVAPS as the first line of noninvasive ventilatory treatment in patients with exacerbations of Chronic obstructive pulmonary disease (COPD) and hypercapnic encephalopathy (GCS < 10), is useful and safe.

Ethics approval required
Old ethics approval format

Ethics approval(s)
School of Medicine Ethics Committee of the Universidad San Francisco de Quito, 03 January 2009, ref: 3012009

Study design

Prospective interventional match-controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Infectious exacerbations of COPD and hypercapnic encephalopathy

Interventions

11 patients with infectious exacerbations of COPD and hypercapnic encephalopathy with GCS < 10 were designated to receive BiPAP S/T with AVAPS.

The control group was then selected from patients in the emergency unit with infectious exacerbations of COPD and encephalopathy (GCS < 10).

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Level of consciousness (Glasgow Coma Scale score)

Key secondary outcome(s)

1. Duration of mechanical ventilation
2. Hospital stay, and
3. Progression (exhaled tidal volume, inspiratory pressure, and arterial blood gases)

Completion date

01/09/2011

Eligibility**Key inclusion criteria**

1. Age > 40 years
2. COPD was diagnosed on the basis of the recommendations of the American Thoracic Society
3. Hypercapnic encephalopathy with GCS < 10 were designated to receive BiPAP S/T with AVAPS
4. The control group was then selected from patients in the emergency unit with infectious exacerbations of COPD and encephalopathy (GCS < 10). Patients were treated immediately and referred to us by doctors who were unaware of the study. Each patient was treated with NIV and was selected according to: Acute Physiology and Chronic Health Evaluation II (APACHE II) score within 4 points, age within 10 points, pH within 0.04, GCS within 2 points, and BMI within 2 points
5. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. A face deformity
2. Obstruction of the upper respiratory tract owing to recent surgery or trauma
3. Alterations in the central nervous system not related to a hypercapnic encephalopathy
4. Cardiogenic pulmonary edema, pneumothorax, pulmonary thromboembolism, hemoptysis, or septic shock
5. Urgent intubation owing to cardiac and/or respiratory arrest, and hemodynamic instability with a systolic arterial blood pressure (BP) of less than 80mmH
6. Other neurological illness

Date of first enrolment

01/02/2009

Date of final enrolment

01/09/2011

Locations

Countries of recruitment

Ecuador

Study participating centre

Geraneos II Mz 3010 Villa 7

Guayaquil

Ecuador

5934

Sponsor information

Organisation

San Francisco de Quito University (Universidad San Francisco de Quito) (Ecuador)

ROR

<https://ror.org/01r2c3v86>

Funder(s)

Funder type

University/education

Funder Name

Universidad San Francisco de Quito (Ecuador)

Results and Publications

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	12/03/2013		Yes	No