ISRCTN05135218 https://doi.org/10.1186/ISRCTN05135218

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

Submission date
07/09/2012

Recruitment status
No longer recruiting

Registration date
18/09/2012

Overall study status
Completed

Last Edited
04/05/2017

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
Level of consciousness (Glasgow Coma Scale score)

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

Overall study start date

01/02/2009

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

Age group
Adult

Sex
Both

Target number of participants
11 x 2

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
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Sponsor information

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

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Sponsor type
University/education

ROR
https://ror.org/01r2c3v86

Funder(s)

Funder type
University/education

Funder Name
Universidad San Francisco de Quito (Ecuador)

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	12/03/2013		Yes	No