ISRCTN96455367 https://doi.org/10.1186/ISRCTN96455367

AVAPS in Acute Respiratory Failure of various etiologies

Submission date	Recruitment status	[_] Prospectively registered
06/07/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/07/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/09/2023	Circulatory System	

Plain English summary of protocol

Background and study aims
Acute respiratory failure occurs when the lungs are unable to remove the carbon dioxide from the lungs. This can be caused by a variety of lung issues such as chronic obstructive pulmonary disease (COPD) (causes the airways to be narrowed), asthma (difficulty breathing), pneumonia (swelling of the lungs), acute respiratory distress syndrome (ARDs) (when fluid buildings up in the lungs), congestive heart failure and interstitial lung disease (diseases affecting the tissue and space around the air sacs of the lungs). The usually treatment is to provide helping breathing. Noninvasive ventilation is a type of breathing support that involves the patient wearing a face mask during sleep which is connected to the machine that supplies a constant steam of pressurised air to help keep the airways open. The settings of the noninvasive ventilation are determined based on clinical evaluation, blood gas, volumes, flow and pressure. This is usually done individually and is different for patients. Having a fixed and preprogrammed setting that is kept constant could be helpful, such as using a BIPAP S/T AVAPS strategy. The aim of this study is to evaluate the results of using the ventilator strategy on patients with acute respiratory failure due to different reasons.

Who can participate?
Adults aged 18 and older with acute respiratory failure.

What does the study involve?
Participants are allocated based on their reason for acute respiratory failure. They are then given the BIPAP S/T AVAPS strategy. This is initially programmed to provide maximal inspiratory positive pressure of 20 cm and a minimum of 12 cm with a positive expiratory pressure of 6-8 cm. Participants are followed up to measure the blood gas levels, severity of diseases, blood pressure, heart rate, respiratory rate and other breathing measures.

What are the possible benefits and risks of participating?
Participants may benefit from using the non-invasive ventilation such as the use of additional medication (sedation) and a not having a tube in the mouth. There are risks of complications with the mask and airway pressures.

Where is the study run from?
Universidad de Guayaquil (Ecuador)

When is the study starting and how long is it expected to run for?
December 2011 to January 2014

Who is funding the study?
1. Universidad San Francisco de Quito (Ecuador)
2. Universidad San Francisco de Quito (Ecuador)
3. Santa Maria Clinic (Ecuador)

Who is the main contact?
1. Dr Killen Briones Claudett
killen.brionesc@ug.edu.ec
2. Dr Michelle Grunauer
mgrunauer@usfq.edu.ec

Contact information

Type(s)
Scientific

Contact name
Prof Killen Harold Briones Claudett

ORCID ID
http://orcid.org/0000-0002-7778-0362

Contact details
The University of Guayaquil (Universidad de Guayaquil)
Facultad de Ciencias Médicas
Av. Kennedy y Av. Delta
Guayaquil
Ecuador
090514

Type(s)
Scientific

Contact name
Dr Michelle Grunauer

ORCID ID
http://orcid.org/0000-0002-5821-7603

Contact details
Av. Interoceánica Km 12 ½ Edificio de Especialidades Médicas PB Hospital de los Valles
Universidad San Francisco de Quito
Quito
Ecuador
-

+593 (0)9 98938210
mgrunauer@usfq.edu.ec

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2011.14 (1)

Study information

Scientific Title
Non-Invasive mechanical Ventilation with pressure support guaranteed with average volume (AVAPS) in Acute Respiratory Failure of various etiologies

Acronym
NIV and AVAPS

Study objectives
The aim of this study is to evaluate if the ventilatory strategy is useful in patients with acute respiratory failure of various etiologies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Teaching and Research Department of the Santa Maria Clinic, 01/12/2010, ref: 2010.14 (1)

Study design
Single-center retrospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
The patients were divided according to the pathology on the basis of which presented the acute respiratory failure: COPD / bronchial asthma / pneumonia / ARDS / congestive heart failure and interstitial disease

Interventions
Participants are allocated to groups based on their type of acute respiratory failure:

Hypercapnic ARF: Obstructive diseases (COPD and bronchial asthma)
Hypoxemic ARF: Pneumonia, ARDS, congestive heart failure, and intestitial lung disease

Participants are then given BiPaP S/T +AVAPS therapy. The ventilatory parameters are initially programmed in the BiPAP S/T mode with AVAPS with a maximal inspiratory positive pressure (IPAP) programmed in the 20 cm H2O device and a minimum programmed IPAP of 12 cm H2O with a positive expiratory pressure (EPAP) of 6-8 cm water.

The programmed tidal volume is 6-8 ml/kg of ideal body weight, using the following formula 55.5 ± 2.3 (inches-60) for men and 45.5 for women + 2.3 (inches) 60) respiratory rate was 14-20 breaths/min, rise time 300-400 ms and inspiratory time was 0.8 - 1.2s. Oxygen supplements are added through an oxygen adapter close to the mask, to keep the SaO2 above 90%. Maximum IPAP, exhaled tidal volume (Vt exh), Vmin and leaks arecontrolled through the ventilator software. This is done using the BiPAP Synchrony with AVAPS and Autotrak (Respironics Inc., Murrysville, Pennsylvania, USA) and a series of Mirage IV (Resmed) face masks.

Participants are followed up to measure the blood gas levels, severity of diseases, blood pressure, heart rate, respiratory rate and other breathing measures.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
BiPAP S/T plus average volume-assured pressure support (AVAPS)

Primary outcome measure
1. Use of NIV is measured using patient records at discharge from hospital
2. Aterial blood gas is measured using an arterial blood gas test (blood test) at baseline, one, 12 and 24 hours of NIV use
3. Severity of disease is measured using the APACHE II (Acute Physiology and Chronic Health Evaluation (APACHE II) score at range (0-71 points)
4. Blood pressure (mm/Hg) is measured using a blood pressure cuff
5. Heart rate is measured using pulse monitors
6. Respiratory rate is measured using the amount of breaths over one minute.
7. Tidal volume (mL) programmed AVAPs is measured using patient records.
8. Levels of IPAP (cmH2O) are measured using patient records

9. Level of EPAP (cmH2O) are measured using patient records
10. Inspiratory time (mseg) is measured using patient records
11. Tidal volume patients (mL) is measured using patient records
12. Radiographic changes are measured at number quadrant divided into four according to the affection
13. Complications (excessive discomfort, nasal ulcer, gastric distension and claustrophobia) are measured using patient records

Secondary outcome measures
1. Days of hospitalisation is measured using patient records at number of discharge
2. Number of endotrachael intubation is measured using patient records at number of intubated patients and their percentage at discharge
3. Death is measured using patient records at time of death

Overall study start date
01/07/2010

Completion date
01/01/2014

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Admitted to the intensive care unit of Santa Maria Clinic
3. Acute respiratory failure due to exacerbation of COPD, asthma, pneumonia, ARDS, congestive heart failure and intestitial lung disease

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
68

Total final enrolment
68

Key exclusion criteria
1. Facial deformity
2. Obstruction of the upper airway by surgery or trauma
3. Alterations in the central nervous system does not relating to hypercapnic encephalopathy

4. Cardiogenic pulmonary edema, pulmonary embolism, pneumothorax, hemoptysis, or septic shock
5. Urgent intubation due to cardiorespiratory arrest and hemodynamic instability with systolic pressure less than 80 mm Hg. 6. Hemodynamic instability
7. Excess of respiratory secretions
8. Non-cooperative or agitated
9. Unable to use the interface device
10. Has had recent surgery of the upper airway,
11. Received NIV with “Do not resuscitate orders"

Date of first enrolment
01/12/2010

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Ecuador

Study participating centre
Universidad de Guayaquil
Ciudadela Universitaria
Guayaquil
Ecuador
5934

Study participating centre
Universidad San Francisco de Quito
School of Medicine
Valle de Cumbaya
Quito
Ecuador
5932

Study participating centre
Santa Maria Clinic
Intensive Care Unit
Lorenzo de Garaycoa 3209 y Argentina
Guayaquil
Ecuador
5934

Sponsor information

Organisation
The University of Guayaquil (Universidad de Guayaquil)

Sponsor details
Ciudadela Universitaria
Facultad de Ciencias Médicas
Av. Kennedy y Av. Delta
Guayaquil
Ecuador
5934

Sponsor type
University/education

Website
https://servicioenlinea.ug.edu.ec/siug/

Organisation
Universidad San Francisco de Quito

Sponsor details
School of Medicine
Valle de los Chillos en Cumbaya
Diego de Robles y Vía Interoceánica
Quito
Ecuador
090514

Sponsor type
University/education

Website
http://www.usfq.edu.ec

Organisation
University of Guayaquil

Sponsor details
-
Guayaquil
Ecuador
-

Sponsor type
Not defined

Funder(s)

Funder type
University/education

Funder Name
Universidad San Francisco de Quito

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Killen Briones Claudett (kyllenbrio@yahoo.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			01/04/2019	No	Yes
Results article		30/12/2021	05/09/2023	Yes	No