

# AVAPS in Acute Respiratory Failure of various etiologies

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<b>Registration date</b> 19/07/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/09/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## 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 builds 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 usual 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 stream 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  
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## Contact information

**Type(s)**  
Scientific

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## **Additional identifiers**

### **Protocol serial number**

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

### **Study type(s)**

Treatment

### **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 interstitial 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 H<sub>2</sub>O device and a minimum programmed IPAP of 12 cm H<sub>2</sub>O 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  $55.5 \pm 2.3$  (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 SaO<sub>2</sub> above 90%. Maximum IPAP, exhaled tidal volume (V<sub>t</sub> exh), V<sub>min</sub> and leaks are controlled 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

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

BiPAP S/T plus average volume-assured pressure support (AVAPS)

### **Primary outcome(s)**

1. Use of NIV is measured using patient records at discharge from hospital
2. Arterial 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 (cmH<sub>2</sub>O) are measured using patient records
9. Level of EPAP (cmH<sub>2</sub>O) are measured using patient records
10. Inspiratory time (msec) 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

### **Key secondary outcome(s)**

1. Days of hospitalisation is measured using patient records at number of discharge
2. Number of endotracheal 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

### **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 interstitial lung disease

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### 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)

## **Organisation**

Universidad San Francisco de Quito

## **Organisation**

University of Guayaquil

# Funder(s)

## Funder type

University/education

## Funder Name

Universidad San Francisco de Quito

# Results and Publications

## 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 (kyllebrio@yahoo.com).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		30/12/2021	05/09/2023	Yes	No
<a href="#">Participant information sheet</a>			01/04/2019	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes