

Use of non-invasive mechanical ventilation with pressure support guaranteed with average volume (AVAPS) in de novo hypoxemic respiratory failure

Submission date 16/07/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 26/07/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 20/06/2019	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Hypoxemic respiratory failure is a condition where there is not enough oxygen in the blood but levels of carbon dioxide are close to normal. Non-invasive ventilation is a form of treatment for acute respiratory failure in which a mask is placed covering the face and mouth of the patient to deliver oxygen. The aim of this study is to test a new noninvasive ventilation strategy in order to find out whether this technique is well tolerated by patients.

Who can participate?

Patients aged 18 and over with hypoxemic respiratory failure

What does the study involve?

All participants are treated with noninvasive ventilation using the new strategy and are evaluated during their stay in ICU and follow-up until discharge from hospital.

What are the possible benefits and risks of participating?

The new technique may avoid the need for endotracheal intubation (breathing tube) with a shorter hospital stay and fewer complications. The risks are related to the facial complications that could arise from the use of the mask (lacerations on the face and nose) and gastric distension (bloating of the stomach) due to the effects of the airway pressure.

Where is the study run from?

1. Santa Maria Clinic (Ecuador)
2. Universidad de Guayaquil (Ecuador)
3. Universidad San Francisco de Quito (Ecuador)

When is the study starting and how long is it expected to run for?

January 2010 to January 2014

Who is funding the study?
Universidad San Francisco de Quito (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
<https://orcid.org/0000-0002-7778-0362>

Contact details
Ciudadela Victoria del Rio Mz 2963 Villa 17
Guayaquil
Ecuador
Postal code: 090514 Guayaquil – ECUADOR Area Code: 5934
+593 (0)989097152
kyllenbrio@yahoo.com

Type(s)
Scientific

Contact name
Dr Michelle Grunauer

ORCID ID
<https://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

Protocol serial number
01/12/2010 serial: 2010.14 (2)

Study information

Scientific Title

AVAPS in de novo hypoxemic respiratory failure

Acronym

NIMV with AVAPS

Study objectives

The strategy of ventilation with BiPAP S/T - AVAPS - pressure (support guaranteed with average volume) is feasible in patients with de novo hypoxemic respiratory failure.

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 (2)

Primary study design

Observational

Study design

Single-center retrospective/prospective non-randomized study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

De novo hypoxemic respiratory failure (not produced by acute exacerbations of COPD, chronic pulmonary diseases or congestive heart failure)

Interventions

The study consists of subjecting patients to noninvasive ventilation using a new strategy that includes the programming of ventilatory parameters in BiPAP S / T AVAPS mode in order to observe if this technique is well tolerated by the patients. All patients were admitted during the period between 01/12/2010 and 01/01/2014, informed consent was obtained from patients and their surrogates if they were not able to respond by themselves. A total of 70 patients were recruited for this study. All patients were evaluated during their stay in ICU and follow-up until discharge from hospital.

Intervention Type

Device

Phase

Not Applicable

Primary outcome(s)

Success or failure of the use of the NIV (expressed as percentage), evaluated during stay in ICU and follow-up until discharge from hospital

Key secondary outcome(s)

Evaluated during stay in ICU and follow-up until discharge from hospital:

1. Days of hospitalization (expressed in days)
2. Proportion requiring endotracheal intubation (expressed as percentage)
3. Death (expressed as percentage of patients)

Completion date

01/01/2014

Eligibility**Key inclusion criteria**

1. Aged 18 years and over
2. Patients who presented with signs of acute respiratory failure at the emergency room (RR >25 breath for minute, use of accessory muscles) for de novo hypoxemic respiratory failure (not produced by acute exacerbations of COPD, chronic pulmonary disease or congestive heart failure) with PaO₂/FIO₂ of mild to moderate as per thresholds defined in the Berlin criteria for the ARDS

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

38

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
4. Urgent intubation due to cardiorespiratory arrest and hemodynamic instability with systolic pressure less than 80 mmHg
5. Hemodynamic instability
6. Excess of respiratory secretions
7. Non-cooperative or agitated

8. Unable to use the interface device
9. Recent surgery of the upper airway
10. Received NIV with "DO NOT RESUSCITATE ORDERS"

Date of first enrolment

01/12/2010

Date of final enrolment

01/01/2014

Locations

Countries of recruitment

Ecuador

Study participating centre**Intensive Care Unit of the Santa Maria Clinic**

Lorenzo de Garaicoa y Capitan Najera

Guayaquil

Ecuador

5934

Study participating centre**Universidad de Guayaquil**

Facultad de Ciencias Medicas

Av. Kennedy y Av. Delta

Guayaquil

Ecuador

Postal code: 090514 Guayaquil – ECUADOR Area Code: 5934

Study participating centre**Universidad San Francisco de Quito**

Facultad de Ciencias de la Salud

Diego de Robles y Vía Interoceánica

Quito

Ecuador

Postal code: 090514 Guayaquil – Ecuador

Sponsor information

Organisation

Universidad de Guayaquil

Organisation

Universidad San Francisco de Quito

Organisation

Universidad Tecnológica Empresarial de Guayaquil

ROR

<https://ror.org/056srs126>

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 and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2018	20/06/2019	Yes	No
Participant information sheet		24/07/2017	27/07/2017	No	Yes