

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/07/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/06/2019	Condition category Respiratory	<input type="checkbox"/> 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?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Study design

Single-center retrospective/prospective non-randomized study

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See additional files

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/01/2010

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

70

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

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Study participating centre**Universidad de Guayaquil**

Facultad de Ciencias Medicas

Av. Kennedy y Av. Delta

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Study participating centre

Universidad San Francisco de Quito

Facultad de Ciencias de la Salud

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Sponsor information

Organisation

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University/education

Organisation

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University/education

Organisation

Universidad Tecnológica Empresarial de Guayaquil

Sponsor details

Sponsor type

Not defined

ROR

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

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 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?
Participant information sheet		24/07/2017	27/07/2017	No	Yes
Results article	results	01/10/2018	20/06/2019	Yes	No