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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

Registration date
26/07/2017

Overall study status
Completed

Last Edited
20/06/2019

Condition category
Respiratory

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

Type(s)
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
Ecuador
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Study participating centre
Universidad de Guayaquil
Facultad de Ciencias Medicas
Av. Kennedy y Av. Delta
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Postal code: 090514 Guayaquil – ECUADOR Area Code: 5934

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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Sponsor type
University/education

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Sponsor type
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