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CO2 gap and weaning outcome from mechanical ventilation

Submission date
27/08/2019

Recruitment status
No longer recruiting

Registration date
06/09/2019

Overall study status
Completed

Last Edited
10/09/2019

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
After recovery from acute events that have led to intubation and ventilation, weaning from mechanical ventilation is the essential and usual component in the management of critically ill patients. Weaning failure, which occurs in approximately 25 to 42% of patients meeting the readiness criteria, is associated with prolonged mechanical ventilation, increased morbidity, and mortality. Thus, early identification of patients that are going to fail the liberation from mechanical ventilation is of paramount importance to improve the outcome of these critically ill patients.
Discontinuation of ventilatory support can be very challenging for clinicians mainly because the pathophysiology of weaning failure is complex and not fully understood. This study aims to investigate the central venous-to-arterial difference in carbon dioxide in patients who fail a weaning trial.

Who can participate?
Patients aged 18 years or older under mechanical ventilation for at least 48 hours who fulfil the inclusion criteria

What does the study involve?
Treatment will be continued as normal. Data will be collected on the success or failure of weaning from mechanical ventilation

What are the possible benefits and risks of participating?
The possible benefits are: It is well known that critically ill patients under mechanical ventilation who fail the extubation are at high risk of getting aspiration pneumonia, increased morbidity, and mortality. Weaning failure still occurs in as high as 40% of patients who already met the standard criteria for weaning as established by different societies of respiratory and critical care medicine. Therefore, looking for new indices that help to predict the weaning outcome accurately is of utmost importance to reduce the incidence of weaning failure, which is associated with high morbidity and mortality. We found that the combination of changes in CO2gap (difference between venous-to arterial PCO2 difference) and ScvO2 (central venous oxygen saturation) during a spontaneous breathing reliably predict the weaning outcome and can assist the Physician in his/her decision to extubate the patient in minimalization the risk of

failure and its associated elevated morbidity and mortality.
Theoretically, there is no risk in participating in this study as the included patients have already venous central and arterial catheters inserted before being included in the study. Also, the decision of extubation was left at the discretion of the attending Physician who was following the standard international criteria of readiness for extubation.

Where is the study run from?
1. Centre Hospitalier de Lens
2. Centre Hospitalier d'Arras
3. Centre Hospitalier de Cambrai

When is the study starting and how long is it expected to run for?
December 2016 to February 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
161205

Study information

Scientific Title
Combination of central venous-to-arterial PCO2 difference and central venous oxygen saturation accurately predict weaning outcome from mechanical ventilation

Study objectives
PCO2 gap is able to accurately predict the weaning outcome from mechanical ventilation in critically ill patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/12/2016, Centre Hospitalier de Lens Comité d'éthique (99 route de la Bassée, 62307, Lens Cedex, France; +33 321691234; bdelepine@ch-lens.fr), ref: 160402

Study design
Prospective multi-center study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Mechanical ventilation

Interventions
A patient was included when readiness to wean criteria were met (see inclusion criteria)

A spontaneous breathing trial (SBT) was then performed, in semi-recumbent patients, on a T-piece with supplementary humidified oxygen to achieve arterial oxygen saturation >90% as measured by pulse oximetry. The duration of the SBT was 60 minutes. Criteria for poor SBT tolerance were:
1. Diaphoresis

2. Use of accessory respiratory muscles
3. RR > 35/min
4. Oxygen saturation by pulse oximetry <90% with FiO2 ≥50%
5. HR >140/min or greater than a 20% increase from baseline
6. Systolic blood pressure >180 mmHg or <90 mmHg
7. Development of cardiac arrhythmias; and/or low level of consciousness (Glasgow Coma Scale score <13).

The decision to stop SBT was made by physicians. Patients who did not tolerate the SBT were reconnected to a ventilator.

Patients who successfully completed the SBT were extubated and followed up for 72 hours. Weaning failure was diagnosed if SBT was aborted because of clinical intolerance or if the patient was extubated but required mechanical ventilation (invasive or non-invasive), because of respiratory failure, within the following 48 hours. Respiratory failure after extubation was defined as the development of at least one of the following:
1. Respiratory acidosis with pH <7.32 and arterial CO2 pressure (PaCO2) >45 mmHg
2. Arterial oxygen saturation <90% with FiO2 >0.5
3. RR>35/min
4. Clinical signs of respiratory fatigue

The management of post-extubation respiratory failure was not protocolized and left to the physician's discretion

Intervention Type
Other

Primary outcome measure
Weaning failure rate from mechanical ventilation defined as the development of at least one of the following:
1. Respiratory acidosis with pH <7.32 and arterial CO2 pressure (PaCO2) >45 mmHg
2. Arterial oxygen saturation <90% with FiO2 >0.5
3. RR>35/min
4. Clinical signs of respiratory fatigue

Secondary outcome measures
None

Overall study start date
17/12/2016

Completion date
20/02/2018

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Under mechanical ventilation for at least 48 hours
3. Satisfied the weaning criteria. The readiness to wean criteria were:
3.1 The resolution or improvement of the underlying cause of respiratory failure for which the

patient was intubated
3.2 Hemodynamic stability, defined as heart rate (HR) < 140/min and systolic blood pressure between 90 and 160 mmHg with no or minimal doses of vasopressors
3.3 Stable respiratory status, defined as oxygen saturation >90% with fraction of inspired oxygen (FiO2) ≤0.4 and positive end expiratory-pressure (PEEP) ≤8 cmH2O, respiratory rate (RR) ≤35/min, spontaneous tidal volume (Vt) >5 mL/kg, ratio of RR/Vt <105/min per liter, and no significant respiratory acidosis
3.4 Adequate mental status (Glasgow Coma Scale score >13)
3.5 Adequate cough.
4. Patients also had to have an arterial catheter and a central line with the tip confirmed by x-ray to be in the superior vena cava near at the entrance or in the right atrium.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
85 patients

Key exclusion criteria
1. Tracheotomized patients
2. Do-not-reintubate orders
3. Pregnancy
4. No informed consent
5. Poor cardiac echogenicity

Date of first enrolment
28/12/2016

Date of final enrolment
19/02/2018

Locations

Countries of recruitment
France

Study participating centre
Centre Hospitalier de Lens
99 Route de la bassee
Lens

France
62300

Study participating centre
Centre Hospitalier d'Arras
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Study participating centre
Centre Hospitalier de Cambrai
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Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01fbc7819

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
30/09/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request