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In-exsufflation mechanics in intubated patients

Submission date 12/11/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 26/11/2013	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/01/2018	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
We are carrying out a study on critically ill intubated (a tube inserted via the nose or mouth to keep the airways open) and ventilated (allowing air into the lungs) patients. The first studies to demonstrate mechanical in-exsufflation (IEM) as an effective technique for draining fluid/mucus were conducted in the 1950s. This technique basically mimics a cough in those patients unable to produce a cough to clear the fluid/mucus. This technique in combination with ventilation has been used widely in neuromuscular disease. There is not a lot of data on the use of IEM devices in the intensive care unit (ICU) setting. Currently the technique to remove fluid/mucus is called endotracheal aspiration; serious complications can sometimes occur. This study aims to find out if the use of an IEM device (CoughAssist E70) with conventional tracheal suctioning will improve the drainage of fluid/mucus in intubated and ventilated patients.

Who can participate?
Adult men and women admitted to the intensive care unit who are critically ill and require intubation and ventilation.

What does the study involve?
Subjects will receive both treatments (in-exsufflation with a device [CoughAssist E70] and conventional tracheal suctioning) in a random order. Subjects will be followed up daily until Day 14 and then until discharge from hospital. Subjects will be contacted by telephone on Day 90.

What are the possible benefits and risks of participating?
We believe that the CoughAssist E70 IEM device when used with conventional suctioning will improve the drainage of fluid/mucus. There is data available to demonstrate the effective use of this technology in critically ill patients, but there is a lack of evidence in the ICU setting. The CoughAssist E70 IEM equipment will be fully tested to ensure safety. Subjects will be closely monitored by trained clinical staff.

Where is the study run from?
Service de Pneumologie et de Réanimation, GH Pitié Salpêtrière Charles Foix, Paris, France

When is the study starting and how long is it expected to run for?
January 2014 to December 2016

Who is funding the study?
Philips Respironics (France)

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
EAME2011CoughAssist023

Study information

Scientific Title
In-exsufflation mechanics in intubated patients: a randomized trial

Acronym
COUGH ICU

Study objectives

The use of an in-exsufflation (IEM) device (CoughAssist E70) with conventional tracheal suctioning will improve the drainage of tracheal secretions in intubated and ventilated patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee to Protect People (Comité de Protection des Personnes Île de France VI)

Study design
Single centre prospective randomized cross-over study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute Respiratory Failure requiring mechanical ventilation and endotracheal tube intubation

Interventions
Inclusion:
1. Demographics
2. Duration of mechanical ventilation before inclusion
3. Pathology requiring intubation, history
4. Severity Score SAPS II and SOFA
5. Clinic: blood pressure, heart and respiratory rates, score consciousness (Glasgow) or sedation (RASS), diagnosis (clinical and radiological)
6. Ventilator settings (mode, pressure, volume, Fraction of Inspired Oxygen [FiO2])
7. Diameter of the endotracheal tube
8. Arterial blood gas

Subjects will then receive both treatments (in-exsufflation [IEM] device [CoughAssist E70] or conventional tracheal suctioning) in a random order.

Daily until extubation or Day 14:
1. Number of aspirations
2. Occurrence of a complication with the waning of a drainage procedure tracheobronchial secretions
3. Volume of sputum collected

4. Score of gravity SOFA
5. Blood gases
6. Settings fan (mode, pressure , volume, FiO2)
7. Occurrence of VAP and atelectasis, pneumothorax, adverse event
8. Score of consciousness and sedation (RASS)
9. Tolerance technique EVA if the patient can respond
10. Lung density measured by impedance

Day 28:
1. Duration of invasive mechanical ventilation
2. Duration of hospitalization in intensive care unit (ICU)

Day 90:
1. Mortality in the ICU
2. Hospital mortality
3. Mortality at the end of the stay

Follow up:
1. Monitoring will be carried out until ICU discharge and hospital discharge to determine the ICU and hospital stay mortality
2. Patients will be contacted by telephone at Day 90 to determine mortality. This review will be conducted by one of the investigators.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The number of drainage procedures for tracheobronchial secretions necessary for 24h

Secondary outcome measures
1. The volume of bronchial secretions collected daily
2. The incidence of ventilator-acquired pneumonia defined by the presence of two of the following three criteria:
2.1. Hyperthermia > 38.3 ° C controlled to 4 hours apart
2.2. Leukocytosis > 10 G / l
2.3. Sputum purulent
And the following two criteria:
2.4. Microbiological documentation as defined in the study protocol
2.5. New X-ray image evaluated by the two-point increase Score Weinberg 26
3. The incidence of atelectasis (radiographic or endoscopic diagnosis)
4. The clinical safety of the technique assessed by a visual analogue rating scale in conscious patients
5. The failure of the test airway defined by the occurrence of:
5.1. Increased heart rate of more than 30/min
5.2. Increased respiratory rate of more than 10/min
5.3. Respiratory distress with clinical signs of struggle
5.4. Change in systolic blood pressure over 30 mmHg
5.5. Desaturation of more than 4% SpO2

5.6. Increased the capnia more than 5 mmHg
6. The failure of extubation is defined by the need for reintubation within 72 hours. Reintubation criteria as defined in the study protocol
6.1. Criterion immediate intubation:
6.1.1. Cardiac or respiratory arrest
6.1.2. Respiratory break with loss of consciousness or dying breath
6.1.3. Psychomotor agitation not controlled by sedation
6.1.4. Dimensions persistent
6.1.5. Inhalation massive
6.1.6. Heart rate < 50/min with somnolence
6.1.7. Severe hemodynamic dysfunction not responding to circulatory expansion and administration of vasoactive drugs.
6.2. Criterion mechanical ventilation in non-invasive ventilation and invasive ventilation in case of persistent non-invasive ventilation after:
6.2.1. Respiratory acidosis with arterial pH > 7.35 or PaCO2 > 45 mmHg
6.2.2. SpO2 < 90% or PaO2 < 60 mmHg with FiO2 Inspirational > 50%
6.3.3. Respiratory rate > 35/min
6.3.4. Disorder consciousness, agitation or asterixis
6.3.5. Clinical signs of respiratory control or exhaustion: use accessory respiratory muscles or swinging thoracoabdominal
7. The duration of invasive mechanical ventilation
8. The length of stay in the ICU
9. The length of hospital stay
10. Mortality in the ICU
11. In-hospital mortality

Overall study start date
01/01/2014

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Patient ventilated on endotracheal tube for less than 7 days
2. Duration of mechanical ventilation predicted > 48h

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40-67

Key exclusion criteria

1. Pre-existing neuromuscular pathology, suspected or proven
2. State of shock uncontrolled defined by the administration of norepinephrine or adrenaline at a dose> 0.3 mcg/kg/min
3. Moderate to severe acute respiratory distress syndrome (ARDS) defined by a PaO2/FiO2 ratio <200 mmHg
4. Undrained pneumothorax
5. Hemoptysis active or less than 15 days
6. Intracranial hypertension
7. Decision to limit or stop the treatment
8. Pregnancy
9. Unable to follow study related procedures as explained by the investigator
10. Minor patient

Date of first enrolment
01/01/2014

Date of final enrolment
01/11/2016

Locations

Countries of recruitment
France

Study participating centre
Service de Pneumologie et de
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Sponsor information

Organisation
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Sponsor type

Industry

ROR
https://ror.org/05jz46060

Funder(s)

Funder type
Industry

Funder Name
Philips Respironics (France)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal approximately end of Jan 2019.

Intention to publish date
31/01/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date