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Routine ventilator disconnection on critically ill patients - how bad is it? A clinical observational study in the intensive care unit at Uppsala University Hospital

Submission date
15/03/2012

Recruitment status
No longer recruiting

Registration date
29/03/2012

Overall study status
Completed

Last Edited
12/08/2015

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and aims
Lung collapse occurs when the positive pressure drops in mechanically ventilated patients with acute respiratory failure. The aim in this study is to investigate whether a short, routine disconnection to change the bacterial filter in a mechanical ventilator circle would affect lung function.

Who can participate?
Critically ill and mechanical ventilated patients who are admitted to an intensive care unit and are above 18 years of age.

What does the study involve?
All participants will receive the same treatment. Before a routine filter change, blood pressure and pulse rate will be registered and a blood sample will be drawn. One hour and fifteen minutes after the filter change the same measurements will be repeated.

What are the possible benefits and risks of participating?
Since this study examines the effect of a routine procedure, no risk (more than in the normal routine care) exists. There are no direct benefits, but participation in the study could lead to gained knowledge in the field of respiratory care. It is also possible that the gained knowledge could help future intensive care patients.

Where is the study run from?
Uppsala Academic Hospital, Sweden

When is the study starting and how long is it expected to run for?
The study will be open to participants from approximately February 2011 until January 2013.

Who is funding the study?
Local hospital grants

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
N/A

Study information

Scientific Title
Routinely ventilator disconnection on critically ill patients - effect on oxygenation and lung function. A clinical observational study in the intensive care unit at Uppsala University Hospital

Study objectives
Even a short disconnection from a ventilator during a daily change of a High-Efficiency Particulate Air (HEPA) filter may cause deterioration of lung function in critically ill patients.

Aim:
To test this hypothesis with the primary end-point of lung function expressed by oxygenation and compliance in a clinical prospective observational study in an intensive care unit (ICU) at Uppsala University Hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board in Uppsala [Regionala etikprövningsnämnden i Uppsala], 09/12 /2010, ref: 2010/317

Study design
Single-centre prospective observational study with consecutive inclusion

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.physix.se:1080/forskning/disc_studyinfo.pdf [Swedish]

Health condition(s) or problem(s) studied
Critically ill patients with an acute respiratory failure treated with mechanically ventilation.

Interventions
Twenty patients admitted to the intensive care unit will be consecutively enrolled in this clinical prospective observational study. The study is approved by the Regional Ethical Review Board in Uppsala, Sweden. Informed consent will be obtained from the next in kin before measurements is made.
Before the routinely filter change tidal volume [Vt], respiratory rate, end-inspiratory plateau pressure [EIP] and PEEP (Positive End Expiratory Pressure, will be registered. Compliance of the respiratory system (Crs) will be calculated as VT/(EIP-PEEP). Both EIP and PEEP is measured after a prolonged pause of 10 seconds. A decrease of Crs could suggest that lung collapse has occurred. The fraction of inspired oxygen [FiO2], blood pressure and pulse rate will be registered and an arterial blood gas sample for determination of PaO2, PaCO2, pH and BE will be drawn from the patient. A decrease in PaO2 could also suggest that lung collapse has occurred. Fifteen minutes and one hours after the filter change the same measurements will be repeated.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

The difference in PaO2 (kPa) between baseline, 15 minutes and 60 minutes after the HEPA filter change.

Secondary outcome measures
The difference in pulmonary compliance between baseline, 15 minutes and 60 minutes after the HEPA filter change.

Overall study start date
14/02/2011

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. Patients with respiratory failure treated in the ICU with controlled mechanical ventilatory support
2. Need for fraction of inspired oxygen ≥ 0.5 and positive end expiratory pressure ≥ 10 cmH2O

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
The aim is to include 20 patients

Key exclusion criteria
1. Patients with spontaneous mechanical ventilatory treatment, patients without an arterial access, 2. Patients without an informed consent from next of kin
3. Pregnant patients
4. Patients under the age of 18
5. Patients that do not meet the inclusion criteria

Date of first enrolment
14/02/2011

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala University
Uppsala
Sweden
75185

Sponsor information

Organisation
Uppsala University Hospital (Sweden)

Sponsor details
Akademiska sjukhuset
Uppsala
Sweden
75185

Sponsor type
Hospital/treatment centre

Website
http://www.uas.se/

ROR
https://ror.org/01apvbh93

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Uppsala University Hospital - Akademiska Sjukhuset (Sweden)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2014		Yes	No