

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/03/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/08/2015	Condition category Respiratory	<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/01apvbh93>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Uppsala University Hospital - Akademiska Sjukhuset (Sweden)

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes