

Effect of nursing procedures in critically ill patients - improving or impairing patient health?

Submission date 14/05/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/06/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/01/2019	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and aims

Intensive care is often a life saving process in critically ill patients. In this condition even a slight change in physiological status could have severe effects. Nursing procedures such as changing the patient's position and removal of secretions from the airways are essential to prevent side effects like pressure sores, contractures (loss of joint motion) and hospital-acquired infections. Nursing procedures may have adverse effects like changes in blood pressure or accidental awakening that may worsen the critically ill patients condition. These procedures are not well investigated to date. Therefore we intend to carry out this study in an attempt to evaluate a potential common problem during intensive care.

Who can participate?

To take part you need to be:

1. Critically ill and mechanical ventilated.
2. Be admitted to an intensive care unit.
3. Aged above 18 years.

What does the study involve?

The study protocol is strictly observational and therefore no intervention will be performed. A researcher not included in the regular care will observe the participant during a twelve-hour period from 06 AM to 06 PM. All observed adverse effects, procedures causing the adverse effects and any interventions that follows an adverse effect will be recorded by the researcher.

What are the possible benefits and risks of participating?

Since this study examines the effect of routine procedures, no added risk exists. There are no direct benefits, but participation in the study could lead to improved knowledge in the field of intensive care. It is also possible that the knowledge gained could help future intensive care patients.

Where is the study run from?

The study is run from Uppsala Academic Hospital.

When is study starting and how long is it expected to run for?

The study will be open to participants, from approximately June 2012 until December 2013.

Who is funding the study?

This study is being funded by Uppsala County Council.

Who is the main contact?

Joakim Engström

joakim.engstorm@akademiska.se

Contact information

Type(s)

Scientific

Contact name

Prof Anders Larsson

Contact details

Uppsala University

Department of Anesthesiology and Intensive Care Medicine

Akademiska sjukhuset

ANIVA Ing70, 1 tr

Uppsala

Sweden

75185

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Adverse effects of nursing procedures in critically ill patients - improving or impairing patient health? A clinical observational study in the intensive care unit at Uppsala University Hospital

Study objectives

Critically ill patients in the intensive care unit suffer from adverse effects during nursing routine procedures (e.g. endotracheal suctioning, position change etcetera).

The aim of the study is to investigate this hypothesis with the primary end-point of alternation in consciousness, respiratory and circulatory parametric changes.

1. Is there any adverse effects from nursing routine procedures in critically ill patients in the intensive care unit?
2. What kinds of adverse effects are there and how often do they occur?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethical Review Board, Uppsala [Regionala etikprövningsnämnden i Uppsala], 15 June 2011, ref: 2011/151.

Study design

Single-centre prospective observational study with consecutive inclusion

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Critically ill patients with an acute respiratory failure treated with mechanical ventilation

Interventions

Sixteen patients admitted to the intensive care unit will be consecutively enrolled in this clinical observational study. Informed consent will be obtained from the next in kin before measurements are made.

The observational session will start at 06.00 AM and proceed for 12 hours. The scientist will not be included in the regular care. The patient will only be included once. Under the 12-hour period the scientist will record all nursing procedures and if any adverse effects occur, time, type of adverse effect and any intervention to reduce the adverse effect will also be recorded. The observational protocol will not record any personal data of the medical or nursing staff.

Data that will be collected in the study protocol is changes in tidal volume [Vt], respiratory rate [RR], end-inspiratory plateau pressure [EIP], SpO₂, blood pressure, pulse rate and RASS [Richmond Agitation Sedation Scale].

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Are there any adverse effects from nursing routine procedures (e.g. endotracheal suctioning, position change, etc) in critically ill patients at an intensive care unit?

Key secondary outcome(s)

What kind of adverse effects are there and how often do they occur?

Completion date

31/12/2013

Eligibility

Key inclusion criteria

1. All patients with respiratory failure treated in the Intensive care unit (ICU) with controlled mechanical ventilatory support
2. Need of fraction of inspired oxygen ≥ 0.45 and positive end expiratory pressure ≥ 8 cmH₂O
3. Need of vasoactive drugs (norepinephrine ≥ 0.05 $\mu\text{g}/\text{kg}/\text{min}$)
4. Not fulfilling any of the exclusion criteria

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients without an intra-arterial access
2. Patients without an informed consent from next of kin
3. Patients with limitation of treatment
4. Pregnant patients
5. Patients under the age of 18

Date of first enrolment

01/06/2012

Date of final enrolment

31/12/2013

Locations**Countries of recruitment**

Sweden

Study participating centre

Uppsala University

Uppsala

Sweden

75185

Sponsor information

Organisation

Uppsala County Council (Sweden)

ROR

<https://ror.org/01dv86r63>

Funder(s)

Funder type

Government

Funder Name

Uppsala County Council (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	01/01/2017	18/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes