ISRCTN73736539 https://doi.org/10.1186/ISRCTN73736539

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

Submission date
14/05/2012

Recruitment status
No longer recruiting

Registration date
06/06/2012

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Patient information material can be found at www.physix.se/forskning/ae_studyinfo.pdf (Swedish)

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 measure
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?

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

Overall study start date
01/06/2012

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 µg/kg/min)
4. Not fulfilling any of the exclusion criteria

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
The aim is to include 16 patients.

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)

Sponsor details
Box 602
Uppsala
Sweden
S-75125

Sponsor type
Government

Website
http://www.uas.se/templates/page____43080.aspx

ROR
https://ror.org/01dv86r63

Funder(s)

Funder type
Government

Funder Name
Uppsala County Council (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	01/01/2017	18/01/2019	Yes	No