

Effect of an analgo-sedation protocol for neurointensive patients: a two-phase pilot study

Submission date 24/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/11/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 29/12/2020	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ingrid Egerod

Contact details
The University Hospitals Center for Nursing and Care Research (UCSF)
Rigshospitalet Dept. 7331
Blegdamsvej 9
Copenhagen
Denmark
DK-2100
+45 3545 7365
ie@ucsf.dk

Additional identifiers

Protocol serial number
2093

Study information

Scientific Title
Effect of an analgo-sedation protocol for neurointensive patients: a two-phase interventional non-randomised pilot study

Study objectives

It was hypothesised that the sedation protocol would promote a shift from sedation-based to analgesia-based sedation, and show signs of improved pain management.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Danish Data Protection Agency, approved on 21/12/2006 (J.nr.2006-41-7419)
2. Danish National Committee on Biomedical Research Ethics, approved on 06/12/2006 (J.nr. KF01-2006-4507)

Study design

Interventional non-randomised controlled single-centre trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Sedation and pain management in mechanically ventilated neurointensive care patients

Interventions

100 participants were recruited while the previous sedation practice was in effect, and new 100 participants were recruited after the introduction of the new sedation protocol (200 participants recruited in total).

The new protocol included the following:

1. Pain medication should be given before a sedative
2. A sedative should be used only if necessary
3. Remifentanyl should be used for short-term sedation
4. Fentanyl should be used for traumatic brain injury

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Remifentanyl, Fentanyl

Primary outcome(s)

1. A shift from sedation-based to analgesia-based sedation (analgo-sedation), assessed from the changes in the use of sedatives and analgesic agents in each patient
2. Improved pain management, assessed daily in each patient using the Pain Intensity (PI) scale

For all primary and secondary outcome measures, the participants were followed-up until they were off mechanical ventilation and sedation.

Key secondary outcome(s)

1. Incidence of late pneumonia. Late pneumonia was defined as pneumonia acquired >48 hours after intubation.
2. Accidental extubations
3. Duration of sedation

For all primary and secondary outcome measures, the participants were followed-up until they were off mechanical ventilation and sedation.

Completion date

01/10/2008

Eligibility**Key inclusion criteria**

1. Both males and females, >17 years old
2. Admitted to the neurointensive care unit (NICU)
3. Tracheally intubated within 24 hours
4. Mechanically ventilated
5. Receiving continuous infusions of sedatives and analgesics

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

215

Key exclusion criteria

1. Potential organ donors
2. Non-sedated and non-intubated patients
3. Patients transferred intubated from other units

Date of first enrolment

01/01/2007

Date of final enrolment

01/10/2008

Locations

Countries of recruitment

Denmark

Study participating centre

The University Hospitals Center for Nursing and Care Research (UCSF)

Copenhagen

Denmark

DK-2100

Sponsor information

Organisation

Copenhagen University Hospital (Denmark)

ROR

<https://ror.org/05bpbnx46>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Copenhagen University Hospital Rigshospitalet (Denmark)

Funder Name

The University Hospitals Centre for Nursing and Care Research (Denmark)

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	01/04/2010	29/12/2020	Yes	No