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

Submission date	Recruitment status	[ ] Prospectively registered
24/10/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/11/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/12/2020	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

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. Remifentanil 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)
Remifentanil, Fentanyl

Primary outcome measure
1. A shift from sedation-based to analgesia-based sedation (analgo-sedation), assessed from the chages 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.

Secondary outcome measures
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.

Overall study start date
01/01/2007

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

Age group
Adult

Sex
Both

Target number of participants

200

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)

Sponsor details
c/o Dr Karen-Lise Welling
Neurointensive Unit 2093
Department of Neuroanaesthesiology
The Neuroscience Centre
Rigshospitalet
Copenhagen
Denmark
DK-2100

Sponsor type
Hospital/treatment centre

Website
http://www.rigshospitalet.dk

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

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