

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

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
24/10/2009	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
05/11/2009	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> 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

### Contact name

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## 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. 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(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?
<a href="#">Results article</a>	results	01/04/2010	29/12/2020	Yes	No