

Costs and effects of strategies to prevent oversedation in Intensive Care patients

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 06/07/2009	Condition category Signs and Symptoms	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR117

Study information

Scientific Title
Randomized trial comparing the effects of BIS monitoring and daily wake up with clinical assessment on ICU length of stay and costs in sedated ICU patients.

Study objectives

Objective:

To compare patient safety, inversely estimated as the duration of Intensive Care Unit (ICU) stay and costs between three groups of patients:

1. Those in whom sedatives will be administered continuously and in whom sedation level will be monitored clinically and with Bispectral Index (BIS) (index group 1)
2. Patients in whom the administration of sedatives will be interrupted daily (index group 2)
3. Patients in whom sedative agents will be administered continuously and in whom sedation level will be assessed clinically (reference group)

Research question:

Which of the three strategies mentioned above is associated with shortest duration of ICU stay and with lowest costs?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Primary study design

Interventional

Study design

Multicentre, randomised, active controlled, parallel group trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Oversedation in intensive care

Interventions

Patients will be randomised to one of the following three arms of the trial:

1. Continuous infusion of sedative agents and clinical assessment of the level of sedation with BIS monitoring (index group 1)
2. Daily interruption of sedative infusions (index group 2)
3. Continuous infusion of sedative agents and clinical assessment of the level of sedation (reference group)

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Duration of ICU stay, which is used as an inverse indicator of patient safety.

Key secondary outcome(s)

1. The duration of mechanical ventilation
2. The number and type of accidentally removed catheters
3. The use and type of additional diagnostic tests to evaluate possible over sedation
4. The number of re-admissions to the ICU
5. The length of hospital stay
6. The score on the questionnaire on stressful events (Rotondi)
7. Cumulative survival from admission to the ICU until three months
8. Direct medical costs of used health care resources and indirect, non-medical costs of lost productivity

Completion date

01/01/2007

Eligibility

Key inclusion criteria

Consecutive ICU patients who are 18 years or older, who are sedated for less than 24 hours and who are expected to need sedation for at least another day.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Patients who have been transferred from another ICU where sedative agents have been administered for more than 24 hours
2. Patients with a decreased level of consciousness (defined as a Glasgow Coma Scale score of 12 or lower immediately before sedatives were administered)
3. Patients with an acute cerebral disease in whom the level of consciousness may decrease during admission

Date of first enrolment

01/12/2004

Date of final enrolment

01/01/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Centre (AMC) (Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organization for Health Research and Development (ZonMw) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration