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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21083

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Critically ill patients requiring continuous intravenous sedation.

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Amsterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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 oversedation;

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.

Study description

Background summary

Background:

Sedatives are frequently administered to Intensive Care Unit (ICU) patients to facilitate mechanical ventilation. As many of these patients have metabolic alterations, oversedation is very common.
Oversedation presents as difficulties in weaning from the mechanical ventilator, which increases the risk of several conditions as well as costs. Currently, the level of sedation is estimated clinically. However, this is impossible once a patient is not responsive due to deep sedation.
The recently developed bispectral index (BIS) monitor may increase accuracy of sedation assessment.

Objective:

To increase patient safety in the administration of sedative agents in the ICU.

Study design:

Multicentre, randomised controlled trial.

Study population - ICU patients from three university hospitals and one non-university hospital in the Netherlands.

Interventions:

Continuous infusion of sedative agents and assessment of the level of sedation with clinical monitoring and the BIS score, the weighted sum of different EEG parameters
(index group 1): daily interruption of sedative infusions
(index group 2): and continuous infusion of sedatives and clinical assessment of the level of sedation (reference group).

Outcome measures:

Duration of ICU stay, inversely indicating patient safety (primary).

Secondary outcomes include:

survival until three months after admission to the ICU, length of hospital stay, frequency of stressful experiences in the patients, and medical and non-medical costs.

Economic evaluation:

A cost-minimisation analysis will be performed including direct, medical costs of used health care resources and indirect, non-medical costs of lost productivity.
Unit costing will be done in accordance with existing Dutch guidelines for health care research.
Patient outcome assessment will be restricted to recollections of stressful events during ICU stay.

Study objective

Objective:

To compare patient safety, inversely estimated as the duration of 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 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?

Study design

N/A

Intervention

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).

Contacts

Public
Academic Medical Center (AMC),
Intensive Care Adults (C3-423),
P.O. Box 22660
M.B. Vroom
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
Scientific
Academic Medical Center (AMC),
Intensive Care Adults (C3-423),
P.O. Box 22660
M.B. Vroom
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands

Eligibility criteria

Inclusion criteria

1. Consecutive ICU patients who are 18 years or older;

2. Patients who are sedated for less than 24 hours;

3. Patients who are expected to need sedation for at least another day.

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 administrated), will also be excluded;

3. Patients with an acute cerebral disease in whom the level of consciousness may decrease during admission.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2004
Enrollment:	600
Type:	Actual

Ethics review

Positive opinion

Date:	14-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL86
NTR-old	NTR117
Other	: N/A
ISRCTN	ISRCTN43010133

Study results

Summary results
N/A