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

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

**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**
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
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

## Study design
Multicentre, randomised, active controlled, parallel group trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Prevention

## Participant information sheet

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

### Secondary outcome measures
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

### Overall study start date
01/12/2004

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
600

### 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 administrated)
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)

### Sponsor details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

### Sponsor type
University/education

### Website
http://www.amc.uva.nl/

### 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

**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