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

Gepubliceerd: 14-08-2005 Laatst bijgewerkt: 13-12-2022

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…

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21083

Bron
NTR

Verkorte titel
N/A

Aandoening

Critically ill patients requiring continuous intravenous sedation.

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum Amsterdam
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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?

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2004
Aantal proefpersonen:	600
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-08-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A