

# Effects of Implementation of a new Pain, Agitation, and Delirium guideline in the Intensive Care Unit.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON23254

### Source

NTR

### Health condition

Treatment of critically ill patients in the ICU is often complicated by the onset of delirium. Delirium is a psycho-organic disorder , characterized by an acute disturbance of consciousness and changes in cognition, often with a fluctuating course. Symptoms of delirium include change in level of awareness, decreased attention span, memory deficit, disorientation, language disturbance and hallucinations. Other symptoms commonly associated with delirium are confusion, agitation, apathy, anxiety, abnormal psychomotor activity, and sleep disturbance. The pathophysiology of delirium is poorly understood, but the onset of delirium is a serious complication. Delirium is an important independent predictor of negative clinical outcomes in ICU patients, including increased mortality, longer ICU stay, higher costs of care and long-term cognitive impairment.

## Sponsors and support

**Primary sponsor:** Atrium Medisch Centrum Parkstad

**Source(s) of monetary or material Support:** Atrium Medisch Centrum Parkstad

## Intervention

## Outcome measures

### Primary outcome

Delirium incidence

### Secondary outcome

ICU stay, hospital stay, mortality, comorbidity, NRS/CPOT score, RASS score, CAM-ICU score.

## Study description

### Background summary

Recently, The American College of Critical Care Medicine provided new guidelines for treating pain, agitation, and delirium in the ICU, in which detection and standardized treatment of pain are important issues. By implementing these new guidelines in our ICU, we expect an improved prognosis of patients and possibly a decrease in the incidence of delirium.

### Study objective

Recently, The American College of Critical Care Medicine provided new guidelines for treating pain, agitation, and delirium in the ICU, in which detection and standardized treatment of pain are important issues. By implementing these new guidelines in our Intensive Care Unit, we expect a reduction in the incidence of pain, and possibly also a decreased incidence of delirium. We present the following research question: Does the implementation of pain measurement instruments and standardized treatment of pain, improve the prognosis of patients in the ICU of the Atrium Medisch Centrum Parkstad, and will that lead to a decrease in the incidence of delirium?

### Study design

Pain detection: Numeric Rating Scale (NRS) or Critical Care Observation Score (CPOT) : 3x/day.

Monitoring depth of sedation: Richmond Agitation-Sedation Scale (RASS): 3x/day.

Detecting delirium: Confusion Assessment Method for the ICU (CAM-ICU): 3x/day.

### Intervention

All ICU patients included in the study will be treated according to the new pain, agitation, and delirium guideline during 12 weeks (group A). Primary and secondary outcomes will be

registered. Data will be compared with earlier results of patients in the ICU receiving care as usual (group B).

## Contacts

### **Public**

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## Eligibility criteria

### **Inclusion criteria**

All patients admitted to the Intensive Care Unit of the Atrium Medisch Centrum Parkstad between November 2014 and February 2015 are treated according to latest Pain, Agitation, and Delirium guideline.

### **Exclusion criteria**

- Age < 18 years
- Pre-existent delirium 24 hours before admittance to ICU
- Richmond Agitation Sedation Score (RASS) -4/-5 during ICU stay
- < 24 hours ICU stay

- Deafness or serious visual impairment
- Unable to speak or understand Dutch language
- Serious mental handicaps
- Pre-existent cognitive impairment or dementia
- Aphasia
- Delirium screening compliance rate <80% during ICU stay

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	17-11-2014
Enrollment:	100
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	13-11-2014
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	NL4697
NTR-old	NTR4902
Other	: METC nr: 14-N-99

## Study results

### Summary results

None.