Delirium Op de PICU studie (DOP-studie).

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27483

Source
NTR

Brief title
DOP

Health condition

Pediatric Delirium
Pediatric Intensive Care Unit

Sponsors and support

Primary sponsor: MUMC+
Source(s) of monetary or material Support: MUMC+

Intervention

Outcome measures

Primary outcome

The primary study parameters are: Delirium yes or no with a positive result after diagnostic testing.

Secondary outcome

During the use of the diagnostic instruments, a few 'points' will be collected in order to test

the cut-off value.

The current use of medication will be documented as well as the reason of admission in order to examine the etiology in retrospect of pediatric delirium.

Study description

Background summary

The pediatric delirium hasn't been studied for a long time. The prevalence is 5 to 35 percent. Because the pediatric delirium, and the delirium in general, results in a longer length of stay with higher mortality rates, it is neccessary to diagnose the delirium as quickly as possible. Because of its fluctuating course it is difficult to diagnose the delirium. A good diagnostic instrument can make diagnosing the delirium easier, faster and more efficient.

In adultpsychiatry there are a few diagnostic instruments which are not validated for children yet. For example the CAM-ICU has resently been adapted for use in children by Wes Ely and collaegues. Before these diagnostic instruments can be used in the PICU they have to be validated first. Our objective is to validate multiple diagnostic instruments, especially the pCAM-ICU. By comparing these instruments, we can develope an algoritm which can be used by nursing staff to diagnose the pediatric delirium as soon as possible so that farmacotherapy can be started. The different diagnostic instruments (PAED, comfort-score, DRS-88/DRS-98, pCAM-ICU) will be used twice a day in critically ill children in the PICU which are non-elective OR longer than 48 hours after an elective operation and in the age of 5 to 17 years. Informed consent is necessary.
Also we will note the patients medications.

There are two research teams: the first team consists of a child psychiatrist and a child neuropsychologist (the golden standard / the reference team) and the second team consists of a senior medical student together with a senior psychology student (the validating team). When the second team finds a pediatric delirium by using the diagnostic instruments, the first team will confirm or reject the diagnosis. When the diagnosis pediatric delirium has been made, farmacotherapy will be started.

(When the child intensivists suspect a pediatric delirium they will contact the child psychiatrist for consultation). Critically ill children on a PICU in the age of 5 to 17 years of age

who are admitted on a non-elective base OR have been staying on the PICU for longer than 48 hours after elective surgery. The primary study parameters are: delirium yes or no with a positive result after diagnostic testing. During the use of the diagnostic instruments, a few 'points' will be collected in order to test the cut-off value.

The current use of medication will be documented as well as the reason of admission in order to examine the etiology in retrospect of pediatric delirium.Eventhough our patientpopulation is critically ill, most of the diagnostic instruments will be observational and only the comfort-score and pCAM-ICU could be considered "invasive / psychological invasive". There will be a short physical contact to measure the muscle tone and some questions will be asked regarding statements or pictures. The CAM-ICU and Comfort-score are already in used in adult intensive care unit's (ICU's), and we expect that the burden will be minimal in children as well.

Study objective

1. We expect that the PAED will be at least as reliable to diagnose a pediatric delirium, compared to the pCAM-ICU;

2. By combining the PAED, Comfort and SOS-score and pCAM-ICU for the diagnosis of pediatric delirium on the PICU, the critical care nurses and staff will be able to diagnose a pediatric delirium in a more reliable and valid manner.

Study design

Twice daily during the stay at the PICU.

Intervention

If the first team suspects a pediatric delirium, they will always and immediately alert the reference rater team in order to confirm the diagnosis of delirium and treat the patient according to pediatric delirium guideline in the MUMC+.

Treatment of pediatric delirium:

As part of the treatment, the patient will be evaluated twice a day for signs of discomfort and stressors noted by the children/nurses/ family. We will also continue to intensify the routine psychosocial protocol as we have done in the past. For the psycho-pharmacological treatment of pediatric delirium Schieveld et al has adapted, by fine tuning a treatment guideline which is currently being used on the PICU of the MUMC+ (23, page 118). For children older than 4, a treatment of risperidone p.o. is also an option. There is limited data available for the treatment of delirium of an age younger than 1.
Patients who have been treated for their delirium will be evaluated six weeks after discharge of the hospital, either in an outpatient face to face meeting or by a telephone interview.

Herewith we ask the parents /caretakers regarding all the dimensions of functioning of the formerly hospitalized child. (E.g emotions- cognition- social functioning- school).

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Eligibility criteria

Inclusion criteria

All non-elective patients admitted to the PICU between the age of 1 and 17, ventilated or non-ventilated, will be screened for eligibility regardless of admitting diagnosis which includes both surgical and medical population. This also regards children who have been admitted to the PICU after an elective surgical procedure and who are still at the PICU after 48 hours.

Exclusion criteria

1. All patients admitted to the PICU on an elective base;

2. Regarding the use of the pCAM- ICU and the neurocognitive items: 3, 5, 6, & 13 of the DRS 88/98:

A. Children less than five years of age, because the pCAM-ICU will require some degree of education and baseline level of functioning of the child;

B. Children of at least five years of age, but with a level of cognition less than five years of age, for the same reasons as given above;

C. Non-Dutch speakers;

D. Children with visual or hearing impairments who are unable to be assessed using the pCAM-ICU.

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):	11-01-2009
Enrollment:	125
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL1957
NTR-old	NTR2065
Other	NL : 28525.068.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Because there are no sponsors there are no arrangements made regarding publications. The participating medical and psychological students however will try to write their final thesis regarding: their participation in this PD study and the main results.