

***The delirium at the PICU study: an evaluation of the usefulness of the pCAM-ICU, PAED and comfort-score for the diagnosis of pediatric delirium at the Pediatric Intensive Care Unit (PICU) of the Maastricht Universitair Medisch Centrum (MUMC+)*.**

A quality of care improvement program

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Deliria (incl confusion)
Study type	Observational non invasive

Summary

ID

NL-OMON33431

Source

ToetsingOnline

Brief title

Delirium at the PICU study

Condition

- Deliria (incl confusion)

Synonym

acute brain dysfunction

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Comfort score, Delirium, PAED, pCAM-ICU

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 necessary 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 adult psychiatry there are a few diagnostic instruments which are not validated for children yet. For example the CAM-ICU has recently been adapted for use in children by Wes Ely and colleagues. Before these diagnostic instruments can be used in the PICU they have to be validated first.

Study objective

Our objective is to validate multiple diagnostic instruments, especially the pCAM-ICU. By comparing these instruments, we can develop an algorithm which can be used by nursing staff to diagnose the pediatric delirium as soon as possible so that pharmacotherapy can be started.

Study design

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, pharmacotherapy will be started.

(When the child intensivists suspect a pediatric delirium they will contact the child psychiatrist for consultation).

Study burden and risks

Even though our patient population 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 use in adult intensive care unit's (ICU's), and we expect that the burden will be minimal in children as well.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

All non-elective patients admitted to the PICU between the age of 5 and 17.

Exclusion criteria

1. Children less than five years of age
2. Children of at least five years of age, but with a level of cognition less than five years of age.
3. Non-Dutch speakers.
4. Children with visual or hearing impairments who are unable to be assessed using the pCAM-ICU.

5. All patients admitted to the PICU on a elective base.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 08-01-2010

Enrollment: 125

Type: Actual

Ethics review

Approved WMO

Date: 02-11-2009

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL28525.068.09