# *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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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...

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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 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.

**Study objective**

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.

**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, farmacotherapy will be started.

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

**Study burden and risks**

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.

# 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

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 08-01-2010 |
| Enrollment: | 125 |
| Type: | Actual |

# Ethics review

Approved WMO

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| 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 |