

# Pharmacogenetics of pain and sedation in critically ill children .

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Relevancy of pharmacogenetic testing for optimizing sedative and analgesic drug therapy in critically ill children will be determined. Pharmacogenetic-based, individualized dosing strategies will be developed to optimize drug therapy.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON30003

### Source

ToetsingOnline

### Brief title

Pharmacogenetics in children

### Condition

- Other condition

### Synonym

pain and stress

### Health condition

pijn en onrust

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

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

## Intervention

**Keyword:** Analgesia, Pediatric, Pharmacogenetics, Sedatives

## Outcome measures

### Primary outcome

Main study parameter is the difference in dosage requirements of sedatives and analgesics of patients with different genetic profiles for pain- and sedation related genes.

### Secondary outcome

Population pharmacokinetic-pharmacodynamic (PK-PD) will be used for modeling to determine the impact of the polymorphisms on the relationship between dose, blood drug concentration (PK) and sedation scores (PD: COMFORT scale, VAS scale, BIS monitoring)

## Study description

### Background summary

Presentation of the problem: pharmacogenetic variation is associated with increased risk of drug therapy failure or drug toxicity.

need for knowledge: Sedatives and analgesics are often prescribed to critically ill children, who show wide variation in their response to these drugs.

Individual cases of drug therapy failure or toxicity in this population are currently \*brushed under the carpet\*, while they could be explained by genetic variation in drug handling and response.

proposed solution to the problem: an evaluation will be carried out in critically ill children to determine how pharmacogenetic variation affects drug response and explains part of observed adverse events and drug failure in

critically ill children receiving sedative and analgesic drugs.

### **Study objective**

Relevancy of pharmacogenetic testing for optimizing sedative and analgesic drug therapy in critically ill children will be determined. Pharmacogenetic-based, individualized dosing strategies will be developed to optimize drug therapy.

### **Study design**

observational study with minimal invasive procedures:

1. population pharmacokinetic-pharmacodynamic study
2. allelic frequency determination

### **Study burden and risks**

Minimal blood sampling i.e. one sample per patient in all patients. In a subgroup of patients repeated blood samples will be taken from an indwelling arterial catheter for pharmacokinetic analysis. The study can only be carried out in this population as results from adults or healthy children can not be extrapolated to this group of patients (critically ill children)

## **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

Children with a need for sedation and/or analgesia.

### Exclusion criteria

Life expectancy less than 24 hours

ECMO

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-10-2006

Enrollment: 800

Type: Actual

## Ethics review

Approved WMO

Date: 26-07-2006

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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	NL12395.078.06