Age dependency of midazolam requirements in a pediatric intensive care unit: a prospective clinical study

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To acquire more insight in the relation between age and pharmacodynamics and more insight in the relation between age and pharmacokinetics of midazolam in children.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON31394

Source
ToetsingOnline

Brief title
midazolam requirements in a pediatric intensive care unit

Condition

- Other condition

Synonym
sleep medication

Health condition

betreft kinderen opgenomen op een kinder intensive care afdeling met een diversiteit aan aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: VUmc fondsenwerving;project KICK

Intervention

Keyword: children, midazolam, pediatric intensive care, sedation

Outcome measures

Primary outcome

- Mean daily dosage of midazolam per day will be comapred between different ages

(Kruskall Wallis test).

- Analysis of pharmacokinetics (plasma concentrations) and pharmacodynamics

(Comfort-B score) with the NON-linear Mixed Effect Modelling (NONMEM).

Secondary outcome

not applicable.

Study description

Background summary

Adequate sedation is an important aspect of care in a Paediatric Intensive Care Unit (PICU). Midazolam is the most widely used sedative agent in critically ill children. Retrospective study shows that midazolam requirements in the PICU are age-related. Prospective studies that investigate this age-related effect in pharmacodynamics of midazolam are lacking. A possible explanation of the age-related variation in sedative effect of midazolam might be found in age-related pharmacokinetic differences

Study objective

To acquire more insight in the relation between age and pharmacodynamics and more insight in the relation between age and pharmacokinetics of midazolam in

children.

Study design

Prospective, observational study, at the PICU and Clinical Pharmacology and Pharmacy, VUmc Amsterdam.

Methods: Demographic data and routinely acquired laboratorial data will be collected of each included patient. Also the total dose of midazolam in milligrams per kilograms per day will be registered. During the first three days after acquiring informed consent, three times a day at fixed hours and when changing the midazolam dosage, a blood sample of ca. 1 ml (max. 2 ml if possible) will be taken. Also while running down the midazolam dosage, blood samples (max. 3 of ca. 1 ml with an interval of ca. 3 hours) will be taken. In the blood samples the concentration of midazolam and her metabolites will be determined. Before each blood taking, the COMFORT-B-score, that measures the depth of sedation, will be determined.

Study burden and risks

The extra burden for the patient is the taking of max. 15 ml of blood via the already existing artery line or central venous line. This means the patient won*t be pricked for this study alone. All the time the amount of blood that is taken will be checked, especially in the youngest children. The actions that are undertaken in this study belong to the normal health care that is provided to all admitted children

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All children, age between 0-12 years, being admitted between July 2007 and July 2008 to the pediatric intensive care unit and to be expected being mechanically ventilated for 48 h and permesiion obtained within 24 h after admission.

Exclusion criteria

If midazolam is not the first line drug for sedation. Use of midazolam as anti-epileptic medication. No arteila line or central venous line present. Known liver or renal function disorders or head trauma or psychomotoric retardation.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-04-2007
Enrollment:	28
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL16584.029.07