Pharmacotherapy on CPB.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26789

Source
Nationaal Trial Register

Brief title
CPB-Pharm

Health condition

congenital heart disease
pediatric population
cardiopulmonary bypass
Pharmacokinetics
Pharmacodynamics

Sponsors and support

Primary sponsor: Erasmus MC
's Gravendijkwal 230
Dept Anesthesiology/Thorax
3015 CE Rotterdam
The Netherlands
Source(s) of monetary or material Support: not supported

Intervention

Outcome measures

Primary outcome

1. Determination of population PK of midazolam, propofol, sufentanil, pancuronium, ranitidine, furosemide, enoximone and dobutamine in the pediatric population;

2. Determination of the relationship between the PK of the medication and clinical parameters as age, cyanotic or acyanotic cardiac defects, cardiopulmonary bypass system used, pump flow rate, liver and renal function and protein concentrations.

Secondary outcome

Determination of the relationship between PK and the clinical effect of aforementioned medication. DNA analysis will be performed to evaluate the influence of gene polymorphisms on the PD of anesthetic and analgesic medication.

Study description

Background summary

Background:

Infants and children undergoing heart surgery with cardiopulmonary bypass (CPB) are exposed to different anesthetics, adjuvants and cardiovascular medications. Not much is known about the pharmacokinetics (PK) and pharmacodynamics (PD) of medication we administer to infants and children on CPB and in the first 36 postoperative hours. Most research has been done in the adult patient and otherwise healthy children not undergoing CPB, but results from those studies cannot just be extrapolated to the pediatric population with congenital heart disease.

Study objectives:

This study is aimed at determining PK and PD of medications routinely used in pediatric cardiac surgery at the Erasmus Medical Centre during and after CPB. The goal is to be able to formulate evidence based directions for dosing of medication on CPB in the pediatric population.

Study design:

The study is a prospective observational study.

Study population:

Pediatric patients undergoing open heart surgery for congenital heart disease with the use of CPB at the department of Cardiothoracic Surgery at the Erasmus Medical Centre.

Endpoints:

Primary goals: Determination of population PK of midazolam, propofol, sufentanil, pancuronium, ranitidine, furosemide, enoximone and dobutamine in the pediatric population.

Determination of the relationship between the PK of the medication and clinical parameters as age, cyanotic or acyanotic cardiac defects, cardiopulmonary bypass system used, pump flow rate, liver and renal function and protein concentrations.

Secondary goals: Determination of the relationship between PK and the clinical effect of aforementioned medication. DNA analysis will be performed to evaluate the influence of gene polymorphisms on the PD of anesthetic and analgesic medication.

Description of burden and risk associated with the study:

The research will be performed on children because results from studies on adult patients cannot just be extrapolated to the pediatric population. Changes in the pharmacokinetic properties of medication on CPB may be different in children due to technical differences in CPB execution, developmental differences in pharmacokinetic handling of medication in children of different age groups and the hemodynamic changes depending on the nature of the congenital abnormalities.

The patient will undergo routine anesthesia and CPB according to Erasmus MC protocol with routinely performed monitoring and blood sampling. Extra blood samples will be drawn from an already present arterial line and the CPB system. This will equal a total amount less than 5 % of the circulating volume of each child on CPB. Urine samples will be collected from a routinely inserted urine catheter as well. This should place minimal burden on the patient.

Study objective

Infants and children undergoing heart surgery with cardiopulmonary bypass (CPB) are exposed to different anesthetics, adjuvants and cardiovascular medications. Not much is known about the pharmacokinetics (PK) and pharmacodynamics (PD) of medication we administer to infants and children on CPB and in the first 36 postoperative hours. Most research has been done in the adult patient and otherwise healthy children not undergoing CPB, but results from those studies cannot just be extrapolated to the pediatric population with congenital heart disease.

Study design

1. Pre CPB sampling of blood and urine;

2. Start CPB sampling of blood and urine;

3. Post CPB sampling of blood and urine;

4. Three times postoperative sampling of blood and urine at 12, 24 and 36 hours postoperative.

Intervention

Blood and Urine sampling.

Contacts

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Eligibility criteria

Inclusion criteria

All pediatric patients 0-18 years old, stratified for age group, undergoing open heart surgery for congenital heart disease with the use of CPB are candidates for inclusion.

The age-groups will be:

1. Neonates 0-30 days old;

2. Infants 30-365 days old;

3. Preschool children aged 1-4 years old;

4. School children aged 4-12 years old;

5. Adolescents aged 12-18 years old.

Exclusion criteria

No informed consent.

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:	Recruiting
Start date (anticipated):	04-07-2012
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-08-2012
Application type:	First submission

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	NL3428
NTR-old	NTR3579
Other	METC ErasmusMC : 2011-400
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A