The impact of rhinovirus infections in paediatric cardiac surgery a prospective cohort study

Published: 15-04-2015
Last updated: 21-04-2024

Primary: To identify whether PCR-proven rhinovirus is a risk factor for prolonged PICU admission in children undergoing cardiac surgery. Secondary: to develop a preoperative algorithm to identify children with increased risk for prolonged PICU…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Observational invasive

Summary

ID

NL-OMON46999

Source
ToetsingOnline

Brief title
RISK (rhinovirus infection & surgery in kids)

Condition

- Congenital cardiac disorders
- Viral infectious disorders

Synonym
common cold, rhinovirus

Research involving
Human

Sponsors and support

Primary sponsor: Medische microbiologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac surgery, paediatric, rhinovirus

Outcome measures

Primary outcome

The primary study parameter is PICU length of stay in per-operative

rhinovirus-positive compared to rhinovirus-negative patients.

Secondary outcome

Secondary outcome parameters are:

• Duration of ventilatory support

• Mechanical ventilation conditions (mean airway pressure, FiO2)

• Antibiotic free days (alive at PICU discharge)

• Need of inotropes (inotrope score)

• Infection parameters

• Hospital length of stay

• Secondary infections

Study description

Background summary

Respiratory infections are considered to carry a potential risk of adverse events in children undergoing surgery.
Rhinovirus is a common cause of respiratory infections and congenital heart disease is a risk factor for severe rhinovirus infection. However, we do not know what the impact of clinical or subclinical rhinovirus infections is on postoperative course following congenital heart surgery in children.
Based on our clinical experience, one case-controlled study, and a case reported in the literature , we hypothesize that paediatric patients with per-operative rhinovirus positive Polymerase Chain Reaction (PCR) testing have a longer paediatric intensive care unit (PICU) admission , compared to children

who test negative.

Study objective

Primary: To identify whether PCR-proven rhinovirus is a risk factor for prolonged PICU admission in children undergoing cardiac surgery.

Secondary: to develop a preoperative algorithm to identify children with increased risk for prolonged PICU admission after cardiac surgery.

Study design

This is a prospective single-center observational cohort study in the Leiden University Medical Center (LUMC).

Study burden and risks

All routine hospital procedures will be followed, including pre-assessment by the anaesthesiologist and cardiopulmonary surgeon. The parents/guardians of the children will be asked to fill out a questionnaire before the operation of their child. In the operating theatre, a nasopharyngeal swab will collected in the children after induction of anaesthesia and thus without any discomfort. Nasopharyngeal sampling bears no clinical risks. Clinical data will be collected daily during paediatric intensive care admission, and date of discharge from PICU and from hospital are recorded.
This is an observational study in children already undergoing anaesthesia and cardiac surgery. The study carries no additional burden, risks or benefit.

Contacts

Public
Selecteer

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Selecteer

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

•Children (<12 year) with a congenital heart disease undergoing elective cardiac surgery
•Written informed consent by parents or guardian

Exclusion criteria

•No informed consent from one of the parents (or the legal representative if applicable)
•Anaesthesiologist or cardiopulmonary surgeon postpones surgery based on routine hospital screening
•Emergency surgery
•Children not admitted to the intensive care unit after cardiac surgery
•Children undergoing a second cardiac operation during the same intensive care stay
•Children with duct-dependent physiology who remain prostaglandin-dependent after the heart operation

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-06-2015
Enrollment:	162
Type:	Actual

Ethics review

Approved WMO Date:	15-04-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	14-08-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-03-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL51483.058.14