The impact of rhinovirus infections in children undergoing cardiac surgery

No registrations found.

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

Summary

ID

NL-OMON27376

Source NTR

Brief title RISK

Health condition

rhinovirus rhinovirus cardiac surgery hart operatie respiratory infection respiratoire infectie post operative complications post operatieve complicaties

Sponsors and support

Primary sponsor: Drs. P.P. Roeleveld Leiden University Medical Center (LUMC) Department of paediatric Intensive Care

Dr. J.J.C. de Vries Leiden University Medical Center (LUMC) Department of Medical Microbiology

Source(s) of monetary or material Support: Drs. P.P. Roeleveld

Leiden University Medical Center (LUMC) Department of paediatric Intensive Care Dr. J.J.C. de Vries Leiden University Medical Center (LUMC) Department of Medical Microbiology

Intervention

Outcome measures

Primary outcome

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

This is a prospective single- center observational study in the Leiden University Medical Center in approximately 250 children (<12 years) undergoing elective cardiac surgery, for congenital heart disease.

The parents/guardians of the children will be asked to fill out a questionnaire, to asses respiratory symptoms in the last weeks, before the operation of their child. In the operating theatre, a nasopharyngeal swab will collected. Clinical data will be collected daily during paediatric intensive care admission, and date of discharge from paediatric intensive care unit and from hospital are recorded. If children are still intubated at day 4 a second nasopharyngeal swab and residual blood will be collected. The samples will be tested for rhinovirus with a polymerase chain reaction.

Main study parameter is the paediatric intensive care unit length of stay in per-operative rhinovirus -positive compared to rhinovirus-negative patients.

Study objective

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 design

day -1: questionnaire

day 0 (operation day) : collection of nasopharyngeal swab

day 4: if still intubated: nasopharyngeal swab will be sampled and scavenge samples blood will be requested at the chemical laboratory

Intervention

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. Clinical data will be collected daily during paediatric intensive care admission, and date of discharge from PICU and from hospital are recorded. Of all the patients still on mechanical ventilation at day 4, an additional nasopharyngeal swab will be sampled and scavenge samples blood will be requested at the chemical laboratory if available. Rhinovirus PCR will be performed on nasopharyngeal swab and blood to determine shedding and viremia.

Contacts

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Eligibility criteria

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
- Pre-operative admission to the neonatology department
- 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 (they will be excluded because they will certainly have a prolonged PICU LOS regardless of a possible rhinovirus infection). For example: hypoplastic left heart syndrome following pulmonary artery banding who will remain on prostaglandins until the next staged operation

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2015
Enrollment:	250
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	11-02-2015
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

RegisterIDNTR-newNL4745

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Register

NTR-old Other **ID** NTR4999 RV-MM-PED-1 : P14.303

Study results