The impact of rhinovirus infections in children undergoing cardiac surgery

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27376

Bron
NTR

Verkorte titel
RISK

Aandoening

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

Ondersteuning

Primaire sponsor: Drs. P.P. Roeleveld
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Department of paediatric Intensive Care

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Dr. J.J.C. de Vries
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Department of Medical Microbiology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary study parameter is post-operative PICU length of stay in rhinovirus positive compared to rhinovirus negative patients.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Children (<12 year) with a congenital heart disease undergoing elective cardiac surgery

• Written informed consent by parents or guardian

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2015
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-02-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4745
NTR-old	NTR4999
Ander register	RV-MM-PED-1 : P14.303

Resultaten