

Viral colonisation- and infection dynamics in preterm neonates admitted at neonatology wards

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Primary ObjectiveTo determine the prevalence of respiratory viral colonization/infection in pre-term born neonates during hospitalisation.**Secondary Objectives**1. To study the relation of viral respiratory colonization with respiratory support2. To...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Viral infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON42600

Source

ToetsingOnline

Brief title

Neoviro study

Condition

- Viral infectious disorders

Synonym

viral infections

Research involving

Human

Sponsors and support

Primary sponsor: Kindergeneeskunde

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: premature neonate, respiratory support, transmission, viral infection

Outcome measures

Primary outcome

Respiratory viral colonization calculated as number of viruses per 7 patient days and proportion of patients colonized with a virus

Secondary outcome

- * Duration of hospitalization
- * Days on respiratory support
- * Quality of viral pathogens
- * Number of infectious episodes and infection dynamics

Study description

Background summary

Viral infections are currently underdiagnosed in neonatal high care wards but might lead to a substantial burden of disease. Limited data are available about the prevalence of viral infections on the high care neonatology wards since routine testing is not performed. Surveillance studies of outbreaks of nosocomial infections in NICU patients report an incidence of 5-6% of all infections (1). This was confirmed by Ronchi et al. who report that 6% of all NICU sepsis evaluations had a respiratory virus detected when evaluated for bacterial sepsis (2). In a study looking for rhinovirus (HRV) infection in neonates, patients carrying HRV were longer hospitalized and had greater use and duration of supplemental oxygen, a prolonged ventilator support and twice the rate of bronchopulmonary dysplasia (3).

Many neonates suspected for bacterial infection have negative blood cultures. In addition, inflammatory markers often fail to distinguish between a bacterial or viral infection (4).

New molecular technologies however could easily facilitate the detection of viruses and could increase our understanding of clinical signs of infection in preterm born neonates without having a bacterial infection.

We know that many neonates do not show obvious signs of infection when carrying

a respiratory virus. Nonetheless, this might lead to longer respiratory support without even noticing its relation. In theory, preventive measures could lead to reduced respiratory support and hospitalization in premature neonates with and without having signs of infection.

A study performed at the neonatal intensive care supports this theory. They showed that nosocomial respiratory viruses were frequent, despite the absence of clinical indicators of illness (5). Also, there was a significant relation with length of hospital admittance and the diagnosis BPD (5).

It was shown that most patients with enteroviral and RSV infections were probably infected by the horizontal route (6). Creating greater awareness of infection risk and hygiene measure may lead to a significant reduction in their occurrence.

Currently we do not know the incidence of viral colonization of patients on a high care ward and its influence on respiratory support and signs of clinical infection. Therefore, this study will look into detail to viral infections among vulnerable neonates and aims to reduce the possible morbidity related to viral infection at this age.

References:

1. Change in epidemiology of health care *associated infections in a neonatal intensive care unit. Nambiar S, Singh N. et al. The pediatric Infectious diseases journal 2002; 21:839-842
2. Viral Respiratory Tract Infections in the Neonatal Intensive Care Unit: The VIRIoN-I study. Andrea Ronchi, MD, Ian C. Michelow, MD et al. The journal of Pediatrics. 2014;165:690-6)
3. Nosocomial Rhinovirus Infection in Preterm Infants. Manuel Steiner, MD; Robert Strassl, MD; Julia Straub, MD; et al. The Journal of Pediatric Infectious Disease Journal. 2012;31(12):1302-4.
4. Detection of Respiratory Viral Infections in Neonates Treated for Suspicion of Nosocomial Bacterial Sepsis. Andr Kieszun, MD; Anne Hansmann; Julia Winter, MD; et al. The pediatric Infectious Disease Journal. 2014;33(1):102-104.
5. Incidence and implications of unrecognized viral respiratory tract infections in premature infants during their birth hospitalization: a prospective surveillance study in two neonatal intensive care units. Nicholas J. Bennett, MD, PhD, Christy M Tabarani, MD et al. The journal of paediatrics 2012; 161 (5):814-818
6. Clinical and Epidemiologic Characteristics of Viral Infections in a neonatal intensive care unit during a 12 year period. Verboon-Macielek, MD, Krediet, MD et al. The Pediatric Infectious Disease Journal 2005;24:901-904

Study objective

Primary Objective

To determine the prevalence of respiratory viral colonization/infection in pre-term born neonates during hospitalisation.

Secondary Objectives

1. To study the relation of viral respiratory colonization with respiratory support
2. To determine the presence of viral respiratory and gastro-intestinal infections among preterm neonates who are suspected for late-onset sepsis.
3. To compare the length of stay of patients with- and without viral colonization

Study design

This study is an investigator initiated prospective cohort study. Infants will be recruited in Dutch secondary teaching hospitals with a high care neonatal ward within the Rotterdam area, starting in the St. Franciscus Hospital Rotterdam.

Study burden and risks

NP washes are a routine procedure done at the neonatology department, collection of feces is not invasive. We do not foresee risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

All premature neonates (AD < 37 weeks) admitted at the high/medium care ward > 1 week old.

Exclusion criteria

There are no specific exclusion criteria.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 17-07-2017

Enrollment: 400

Type: Actual

Ethics review

Approved WMO

Date: 06-10-2015

Application type: First submission

Review commission:

MEC-U: Medical Research Ethics Committees United
(Nieuwegein)

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	NL54455.101.15