Detection of infectious virus particles using viable impactor sampling in room air surrounding children with airway infections

Published: 28-03-2017
Last updated: 12-04-2024

Objective: To study the relation between PCR positivity of nasopharynx samples and subsequent shedding of infectious airborne viruses during the course of a respiratory infection in children

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

Summary

ID

NL-OMON53039

Source
ToetsingOnline

Brief title
IMPACTOR

Condition

- Viral infectious disorders

Synonym
influenza, pneumonia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

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

Intervention

Keyword: children, impactor, viruses

Outcome measures

Primary outcome

Main study parameters/endpoints: Primary end point: Time to negativity of viruses in the nasopharynx compared to infectious airborne virus in the room air.

Secondary outcome

Secondary Endpoints: 1) Particle size of infectious viruses captured by viable impactor air sampling. Particle size will serve as a proxy for route of transmission. 2) Relation between clinical parameters and the load of infectious respiratory viruses in the nasopharynx and air

Study description

Background summary

SUMMARY
Rationale: Viral respiratory tract infections are a leading cause of morbidity and mortality worldwide. Most affected are young children. Despite the huge impact of viral respiratory infections on global health and economy, transmission routes have not been characterized in great detail. Airborne transmission of respiratory in viruses occurs via aerosols (<5µm) and/or respiratory droplets (>5µm). Aerosols can be suspended in the air for a long period of time. This enables them to travel for meters. Respiratory droplets are too big to remain in the air for a long period of time and consequently are not capable of traveling through the air for more than 1 meter. These routes of transmission may be different between different viruses. In addition, it is unknown if viruses remain to have the ability to be infectious during the course of disease. Increased knowledge on the exact mode of transmission may

allow to optimize hospital infection prevention control.

Study objective

Objective: To study the relation between PCR positivity of nasopharynx samples and subsequent shedding of infectious airborne viruses during the course of a respiratory infection in children

Study design

Study design: Observational study

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: This study entails minimal harm. Although, nasopharyngeal swabs may be troublesome for children. This study can only be carried out in young children because of specific differences in children and adult immune responses (absence of specific immune response) and disease phenotype (bronchiolitis vs pneumonia). Data obtained from this study may help to further strengthen the evidence on how to prevent these (nosocomial) infection from which the paediatric population at large may benefit.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

- Admitted for SARI, defined as respiratory tract infection necessitating hospitalization.
- Tested qRT-PCR positive for RSV, HMPV, PIV and/or Influenza A+B (co-infection allowed)
- Written Informed consent obtained
For paramyxovirus infections: Children in the age range of new-born until two years hospitalized in the Sophia Children*s Hospital or Delft. Older children are expected to have been infected by those viruses and thus have acquired a pre-existing immune response which will influence the level of replication and subsequent shedding. Therefore children > 2 years are excluded from this study.
For influenza virus infections: Children in the age range of new-born until five years hospitalized in the Sophia Children*s Hospital or Delft. It has been shown that primary infections with influenza viruses occur later than infections caused by paramyxoviruses. Therefore, children until the age of 5 years are included in this study.

Exclusion criteria

- no written parental informed consent, NB: Co-morbidity is not excluded since we study real-life viral transmission routes

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):	22-02-2018
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	28-03-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-02-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-12-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-12-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL59998.078.16