The course of viral respiratory tract infections in young children

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1. To investigate the etiology and incidence of respiratory tract infection in children younger than 6 years of age.2. To investigate the course of respiratory tract infections in children younger than 6 years of age.3. To investigate the clinical...

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

Summary

ID

NL-OMON30390

Source ToetsingOnline

Brief title RSVP2 study

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym

viral respiratory tract infection

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: vergoeding is aangevraagd bij Stichting tot Steun Emma

Intervention

Keyword: children, PCR, respiratory tract infection, respiratory virus

Outcome measures

Primary outcome

- 1. respiratory virus multiplex PCR
- 2. clinical symptoms

Secondary outcome

NVT

Study description

Background summary

Respiratory tract infections in young children are often caused by respiratory virusses. The current method to diagnose viral respiratory tract infections is by use of conventional methods such as immunnefluorescence, immunoblot and cell culture of the nasopharyngeal washes.

The past few years the Polymerase-Chain-Reaction (PCR) has been set up for more sensitive and rapid detection of respiratory virus detection in the nasopharyngeal washes (1,2).

In 2006 the PCR methode has been set up in the AMC and a couple of respiratory virusses such as enterovirus, influenza A en B, adenovirus, coronavirus (1 t/m

- 4) humane metapneumovirus, RSV(A&B), parechovirus, parainfluenza virus (1 t/m
- 4) and rhinovirus acn be evaluated simultaneously by the multiplex-PCR method.

In a previous pilot study we evaluated the clinical symptoms and respiratory virusses by multiplex-PCR of children under 6 years of age admitted at the Emma Children's Hospital for a presumed respiratory tract infection. The final data are currently being analysed.

The purpose of this study is to evaluated in more depth the incidence and etiology of respiratory tract infections in children under 6 years of age admitted at the Emma Children's Hospital for a presumed respiratory tract infection. Furthermore the course of respiratory tract infections will be evaluated in these children.

The duration of detection of respiratory virusses in nasopharyngeale washes and the clinical symptoms will be investigated.

A second part of the study is focused on the clinical consequence of a positive

detection of respiratory virusses in nasopharyngeal washes. For this purpose the recovery of respiratory virusses from nasopharyngeal washes from children without respiratory tract symptoms will be compared to recovery of respiratory virusses from nasopharyngeal washes from children with a presumed resipratory tract infection.

Study objective

1. To investigate the etiology and incidence of respiratory tract infection in children younger than 6 years of age.

2. To investigate the course of respiratory tract infections in children younger than 6 years of age.

3. To investigate the clinical consequence of a positive respiratory virus PCR from nasopharyngeal washes from children without respiratory tract symptoms.

Study design

Children admitted at the Emma Children's hospital with a probable respiratory tract infection are routinely evaluated by testing the nasopharyngeal washes for respiratory virusses. These children will be included in the study and a clinical symptome questionaire is completed by the pediatrician. A follow-up sample of a nasopharyngeal wash will be perfomed on day 3 and at day 7-14 and again a clinical symtom questionair is completed.

The nasopharyngeal washes will be evaluated by immunefluorescence, immunoblot and multiplex PCR.

To gain more insight in the clinical consequence of a positive respiratory PCR from a nasopharyngeal wash from children under 6 yeras of age without respiratory tarct symptoms, nasopharyngeal washes will be performed from children under 6 years of age that visit the outpatient clinic of the Emma Children's Hospital for outer purposes tha respiratory tract complaints. Simultaneously a clinical symptom questionaire will be filled out. This study will be performed during teh wintermonths from december until march. From an average of 150 patients nasopharyngeal washes are being performed annually in the Emma Children's Hospital in the AMC. In this study we will include 100 patients and 100 control studysubjects.

Study burden and risks

The performance of a nasopharyngeal washes causes a short-lasting unpleasant feeling in teh nose. In this study a total of three nasopharyngesl washes will be performed and in the control subject only onenasopharyngeal wash. This is a minimal burden and has only minimal risk. The nasopharyngeal washes are being performed by trained staff.

Contacts

Public Academisch Medisch Centrum

meibergdreef 5 1105 AZ Amsterdam Nederland **Scientific** Academisch Medisch Centrum

meibergdreef 5 1105 AZ Amsterdam Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

1. Children younger than 6 years of age, admitted at the Emma Children's hospital with a presumed respiratory tract infection

2. Children younger than 6 years of age, admitted at the Emma Children's hospital for another cause than a respiratory infection but with a presumed secundary respiratory infection

3. Children younger than 6 years of age who visit the outpatient clinic of the Emma Children's Hospital for other reasons than presumed respiratory tract infections.

Exclusion criteria

Children older than 6 years of age

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	200
Туре:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

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.

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In other registers

Register

ССМО

ID NL15289.018.06