Venturius study
Epidemiology, genetics and immunology of viral lower respiratory tract infections in children.

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Discover diagnostic biomarkers for disease severity. Increase the insight in the epidemiology of viral infections in the primary, secondary and tertiary care facilities and in the pathogenesis of and immunological response against viral infections...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON34042

Source
ToetsingOnline

Brief title
Venturius study

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
Lower respiratory tract infections

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: via het VIRGO consortium (ministerie en EU).

Intervention

Keyword: acute lower respiratory tract infection, biomarker, epidemiology, virus host interaction

Outcome measures

Primary outcome

Identification and validation of genes and proteins that can be used as

diagnostic biomarkers.

Secondary outcome

1. To study the epidemiology of acute LRTI*s in children presenting at primary,

secondary and tertiary care facilities. We specifically analyse:

a) The distribution of the causative viruses at the three levels of

care facilities.

b) The individual role of the various viruses in causing respiratory

tract disease in children.

c) The burden of disease by the various viruses on the health care

facilities.

2. Identification of viral host interactions and factors influencing

susceptibility for viral infections and / or severity of disease.

3. Identification of novel respiratory viruses.

Study description

Background summary

Viral lower respiratory tract infections (LRTI*s) are a leading cause of morbidity and mortality in young children. The most commonly identified viruses are Respiratory Syncytional Virus (RSV), rhinovirus, parainfluenzavirus, human metapneumovirus and influenzavirus. We expect that additional novel viruses may be discovered in the near future. Currently, insight in the clinical epidemiology of viral respiratory infections in children is limited, due to the fact that studies have focussed on groups of children presenting either at primary care facilities or in the hospital. In addition, the variability in disease severity caused by a particular virus is not well understood, neither is the interaction between virus and host at the molecular and cellular levels. A better understanding of the pathogenesis and immune response of the host is very important for the development of new therapeutic and preventive strategies and optimalisation of diagnostic tools (biomarker discovery).

Study objective

Discover diagnostic biomarkers for disease severity. Increase the insight in the epidemiology of viral infections in the primary, secondary and tertiary care facilities and in the pathogenesis of and immunological response against viral infections.

Study design

This is a prospective descriptive multi-centre study for viral LRTIs in children. We expect to include 1000 children (0-6 years) presenting at the primary, secondary and tertiary care facilities during three consecutive years. Children with an acute viral LRTI will be scored on clinical symptoms, the need for nasogastric feeding and/or oxygen supplementation. Nasopharyngeal aspirates (NPA) will be analysed for the presence of viruses and bacterial colonisation. Samples from patients that remain negative will be used for the detection of novel viruses. Blood samples (6 ml) will be obtained in hospitalised children. 3 ml. will be used for transcriptome analysis, the other 3 ml. will be used for immunological assays. We will also study the effect of single nucleotide polymorphisms on disease severity and susceptibility. This last part will focus only on RSV infections.

Study burden and risks

In this study we will include children as subjects. Young infants and children have an immature immune response. This is the reason why viral infections are often more severe in young children in comparison with older children and

adults, resulting in a higher morbidity and mortality. Therefore this study is group related.
In all children an oral swab and a nasopharyngeal aspirate will be taken. These procedure are not painful. A NPA is not pleasant for a child, however it is a fast procedure. Children who have been admitted are asked for a 6 ml. blood sample. This is often standard procedure (69% in a previous study). In these cases only the amount of blood drawn is increased without performing an extra puncture. With local anaesthetics the discomfort of a venapuncture will be diminished. A small hematoma might occur. No more than two attempts will be taken to draw blood. When a child is admitted because of severe LRTI, an additional blood sample and NPA will be asked 4 to 6 weeks after hospital admission. There are no direct or only small benefits of this study for the participating children and their parents. The benefits may be related to the future development of novel diagnostic and therapeutic tools, including the development of vaccines. The confirmation of an viral origin of disease may lead to an earlier discontinuation of antibiotics or less antibiotic prescriptions. Also for parents it may be comforting to know which virus causes their child*s illness.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Kapittellaan 29
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Kapittellaan 29
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Patient younger than 6 years. (meaning not older than five years)
Clinical signs of a lower respiratory tract infection:
Tachypnea OR
Subtractions or nasal flaring OR
Wheezing OR
Apnoea

Exclusion criteria

No informed consent. Corticosteroid use (in the previous 6 weeks, exception start within 24 hours), known primary or acquired immunodeficiency, children using immunosuppressive medications.
o Exclusion criteria for blood drawing for transcriptomics: blood transfusion. If blood transfusion in history: natriumheparin tube only.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-11-2010

Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO Date:	02-11-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL32886.091.10