Virus interactions in the respiratory tract; a cohort study with children

Published: 10-09-2021
Last updated: 21-09-2024

To quantify the strength and direction of interactions between important respiratory virus infections in young children

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

Summary

ID

NL-OMON54063

Source
ToetsingOnline

Brief title
VIOOL

Condition

- Viral infectious disorders

Synonym
Respiratory infections

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Children, Respiratory infections, Virus interactions

Outcome measures

Primary outcome

(Co-)occurrence, timing and virus species of respiratory infection as detected

by PCR analysis of weekly nasal swab specimens.

Secondary outcome

Presence and severity of respiratory and systemic symptoms compatible with

virus infection. Occurrence of acute respiratory illness (ARI) is based on

daily symptom monitoring.

Study description

Background summary

Prevention of virus induced acute respiratory infection (ARI) is a public health priority. As different respiratory virus infections can interact with each other, prevention of one virus by vaccination may influence occurrence of other virus infections. In this project, we will quantify such interactions between respiratory viruses by longitudinally studying a cohort of young children.

Study objective

To quantify the strength and direction of interactions between important respiratory virus infections in young children

Study design

This is a prospective observational cohort study

Study burden and risks

This study is observational in nature. There will be no direct benefit to research participants. The study includes biological sampling. The results of the tests done on these samples may not contribute to improving the participant*s health. Minimal inconvenience and discomfort to the participant

may arise from study visits and biological sampling.

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)
Newborns

Inclusion criteria

Age older than 6 weeks and less than 4 years
AND
1) have older siblings or 2) attend daycare.
AND
Live within 30 minutes drive from UMCU (by car) and have access to a fever thermometer

Exclusion criteria

recurrent respiratory tract infections and are treated with antibiotic profylaxis
OR
known immunodeficiency
OR
chronic lung disease that increases susceptibility to infection (e.g. cystic fibrosis)
OR
congenital anomalies of the airways

Parents/guardians have insufficient comprehension of Dutch language (all study communication and questionnaires are in Dutch language)
A sibling already participating in the study

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-10-2021
Enrollment:	225
Type:	Actual

Ethics review

Approved WMO

Date:	10-09-2021
Application type:	First submission

Review commission:	METC NedMec
Approved WMO Date:	22-06-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-08-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-07-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
ClinicalTrials.gov	NCT05318235
CCMO	NL78424.041.21