Effects of a severe RS infection in the first year of life on childhood health and quality of life

Published: 10-11-2022 Last updated: 17-01-2025

The aim of the study is to determine whether children who have been admitted to the ICU for an RSV infection in their first year of life and now are at school age:1. have more respiratory complaints than controls (based on a short questionnaire...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Ancillary infectious topics
Study type	Observational invasive

Summary

ID

NL-OMON51581

Source ToetsingOnline

Brief title Follow up RSV after 6 years

Condition

- Ancillary infectious topics
- Respiratory tract infections

Synonym Respiratory syncytial virus lower respiratory tract infections, RSV

Research involving Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen **Source(s) of monetary or material Support:** Revafonds

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Intervention

Keyword: follow up, mutible breath washout, PICU, quality of life, Respiratory Syncitial Virus, spirometry

Outcome measures

Primary outcome

LCI

Secondary outcome

Number of children in both groups with specific symptoms such as coughing,

wheezing and shortness of breath

Number of children in both groups diagnosed with asthma

Total score, the psychosocial health score and the physical health score

VmaxFRC vs FEV1,

LCI at 1-2 years compared to LCI at 6 years

FEV1, (abs/ %pred/ z-score) FVC, (abs/ %pred/ z-score) FEV1/FVC, (%) FeNO,

Sex

Age in years

Length/height in centimeters / / length sd

Weight in kilograms / weight in height sd

Medication use

Smoking of parents

Family history for asthma

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Study description

Background summary

98% of children have had an infection with the respiratory tract syncytial virus (RSV) at the age of 2 years. The RS virus causes infections of the respiratory tract, including nose, throat, trachea and lungs. Depending on the severity of the infection, symptoms range from a cold to a severe respiratory distress. A small part of the children (10%) needs hospitalization for the treatment of a bronchiolitis or pneumonitis with RSV as the causative agent. These children have a 30% higher risk of asthma-like symptoms such as wheezing and have often poor lung function at school age. It is unclear whether RSV affects the development of asthma or whether children with asthmatic predisposition

are at risk for a more severe course of RSV bronchiolitis. A follow-up at the age of 6 years or older will be carried out within the UMCG.

In 2012, we started a follow up program in which children with RSV bronchiolitis who were admitted to the ICU were invited after 6 months for a consultation with an infant lung function.

Study objective

The aim of the study is to determine whether children who have been admitted to the ICU for an RSV infection in their first year of life and now are at school age:

1. have more respiratory complaints than controls (based on a short questionnaire based on the ISAAC for 6/7 year olds)

- 2. are more to have asthma than the general population (ISAAC)
- 3. experience a comparable quality of life to controls (PedsQLTM questionnaire)

4. have an impaired lung function compared to healthy controls (Spirometry / MBW / FeNO)

and whether

5. early lung function predicts school-age lung function.

Study design

observational with invasive test (reversibility with salbutamol)

Study burden and risks

Load up to 120 minutes for completing questionnaires and performing lung function tests. No risk. The study cannot be performed in any other age category. There is a chance that the lung function tests will show indications of treatable conditions such as asthma.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Children (2-11 years)

Inclusion criteria

For patients 1-born between 2011-2016, at time of measurement 6 years or more 2-hospitalized due to RSV at the PICU between 2012-2016 3-participated at follow up program 4-able to perform spirometry and MBW For controls: 1 and 4

Exclusion criteria

-Younger than 6 years -congenital pulmonary disease

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	03-03-2023
Enrollment:	84
Туре:	Actual

Ethics review

Approved WMO Date:	10-11-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-12-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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 CCMO **ID** NL79581.042.22