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

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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...

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|---|---|
| **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

## 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

# 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

-not able to perform spirometry or MBW

# 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 |
| Type: | Actual |

# Ethics review

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|---|---|
| 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 | ID |
| --- | --- |
| CCMO | NL79581.042.22 |