# Neolifes-Lungs: the effect of preterm birth on lung function of the children at the age of 6 months

Published: 26-11-2015
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Objective: to obtain lung function parameters in infants born preterm at the age of 6 months and to evaluate risk factors for impaired lung function

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Neonatal respiratory disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON42563

**Source**
ToetsingOnline

**Brief title**
Neolifes-Lungs

### Condition

- Neonatal respiratory disorders

**Synonym**
respiratory problems in children born preterm

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W,Stichting Vrienden Beatrix Kinderziekenhuis

## Intervention

**Keyword:** infants, lungfunction (LCI), prematurity, VLBW

## Outcome measures

### Primary outcome

Main study parameters/endpoints: Lung Clearance Index (LCI), airway resistance

(R), functional residual capacity( FRC) and maximal flow at FRC (VmaxFRC)

### Secondary outcome

1. Does high LCI at the age of 6 months predict more respiratory symptoms and

hospitalisations due to respiratory problems in the follow up period (first

year of life)?

2. Is het possible to determine perinatal/ neonatal riskfactors for high LCI at

the age of 6 months?

# Study description

### Background summary

Rationale: The NeoLifeS cohort comprises preterm children born before 30 weeks* gestational age, and /or birth weights below 1000 grams. These children often have complex health problems after birth and are always treated in a Neonatal Intensive Care Unit for at least several weeks. Several health problems may occur in these children during the following years when they grow up, including respiratory symptoms and impaired lung function. By entering all clinical and follow-up data from birth onwards into a single database, risk factors for the health problems might become evident.

### Study objective

Objective: to obtain lung function parameters in infants born preterm at the age of 6 months and to evaluate risk factors for impaired lung function

### Study design

Study design: observational study

**Study burden and risks**

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden and risks are low. We perform these tests every week at the pediatric lung function department without complications. The patient will have to stay several hours more in the hospital for these lung function tests compared to the patients that only have their regular follow up visit. A benefit could be that lung function impairment will be determined very early.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Children (2-11 years)

### Inclusion criteria

The NeoLifeS cohort comprises preterm children born before 30 weeks* gestational age, and /or birth weights below 1000 grams.

### Exclusion criteria

ill (fever) at the moment of the lung function test
respiratory tract infection
oxygen or feedtubes

## Study design

### Design

**Study type:** Observational non invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 02-11-2016 |
| Enrollment: | 135 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 26-11-2015 |
| Application type: | First submission |
| 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 | NL54534.042.15 |