

# The effects of birth after 32-36 weeks of pregnancy on the lung function of children at the age of 12

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON26209

### Source

Nationaal Trial Register

### Brief title

Follow up study PINKELTJE-cohort

### Health condition

Preterm birth (prematuriteit)

Asthma (astma)

Lung function (longfunctie)

Exercise capacity (inspanningscapaciteit)

Lung Clearance Index (LCI)

## Sponsors and support

**Primary sponsor:** UMCG

**Source(s) of monetary or material Support:** SAB (Stichting Astma Bestrijding)

## Intervention

## Outcome measures

### Primary outcome

Spirometrie : FVC, FEV1, FEV1/FVC, FEF25, FEF50, FEF75, PEF

Ergometrie : Hartfrequentie, ademhalingsfrequentie, maximalebelasting, VO<sub>2</sub>rust, maximale ademfrequentie, VT, VTmax, VEmax, ventilatoire reserve, VO<sub>2</sub> op de anaerobe drempel (AD), VO<sub>2</sub>max, AD, AD/VO<sub>2</sub>,  $\Delta$ VO<sub>2</sub>/ $\Delta$ WR, respiratory exchange ratio, Borg score

LCI : LCI, Scon, Salv

## **Secondary outcome**

no

# **Study description**

## **Background summary**

There has been much research into lung problems in extremely preterm children. A "forgotten group" is the group of children born between 32 and 36 weeks gestation. Research shows that at age 5, these children do indeed have respiratory symptoms, and report a doctor's diagnosis of asthma more often. This study is to determine how these children are at the age of 12 in the respiratory field. To investigate this, we use questionnaires, LCI, spirometry and exercise testing.

## **Study objective**

The hypothesis is that moderate and late preterm infants at age 12 reported more symptoms consistent with asthma and use more asthma medications, as well as a poorer lung function, exercise capacity and Lung Clearance Index than healthy peers.

## **Study design**

March 2014: authorization procedure Metc

September 2014: Sending information letters to parents

September 2015- January 2015: Planning and performing measurements

January 2015: analyze data

## **Intervention**

Questionnaires (general, ISAAC, PAQ C)

Ergometrie

Spirometrie

Lung Clearance Index

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

Research group

- Born between 32 and 36 +6 weeks of gestation

- From one of the three northern provinces (Drenthe, Groningen and Friesland)

#### Control group

- Born after 37 weeks gestation
- From one of the three northern provinces (Drenthe, Groningen and Friesland)

### Exclusion criteria

#### Research group

- Duration of pregnancy precisely determined by ultrasound
- Physical inability to carry out fietsergometrietest
- Birth Defects
- Illness or fever at the time of measurement

#### Control group:

- Duration of pregnancy is not exactly determined by ultrasound
- Physical inability to carry out fietsergometrietest
- Birth Defects
- Use of bronchodilators
- Illness or fever at the time of measurement

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2014
Enrollment:	80
Type:	Anticipated

## Ethics review

Not applicable	
Application type:	Not applicable

## 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
NTR-new	NL4444
NTR-old	NTR4567
Other	: not yet available

## Study results