

# Development of the cardiovascular and respiratory system. Follow-up at the age of 3 years.

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The research question of this study: Is there an association between the respiratory and cardiovascular system in early childhood? If there is an association, what are its determinants?

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Respiratory tract infections
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON37948

### Source

ToetsingOnline

### Brief title

Whistler 3

### Condition

- Respiratory tract infections
- Vascular hypertensive disorders

### Synonym

Cardiovascular and Respiratory disease

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Cardiovascular, Childhood, Respiratory

## Outcome measures

### Primary outcome

The primary study parameters of the respiratory system are the interrupter resistance and nocturnal wheezing and saturation.

The primary study parameters of the cardiovascular system are the pulse wave velocity and the systolic function of the right and left ventricle.

### Secondary outcome

The secondary study parameters of the respiratory system are lung function at the age of 4 weeks and information of visits to the general practitioner.

The secondary study parameters of the cardiovascular system are nocturnal heart rate, steroid hormone level in saliva, blood pressure and blood pressure at the age of 4 weeks.

## Study description

### Background summary

Early life problems of the respiratory system are the most common type of disease in infancy. Cardiovascular diseases are the number one cause of morbidity and mortality in many populations. In adulthood several associations have been described between the cardiovascular and respiratory system. By our knowledge, the relation between the cardiovascular and respiratory system has not been studied in healthy children. In this study we further want to explore this association in early childhood. It is important to get a better understanding of this association in early childhood with regard to prevention of cardiovascular diseases.

## Study objective

The research question of this study:

Is there an association between the respiratory and cardiovascular system in early childhood? If there is an association, what are its determinants?

## Study design

This study has a cross-sectional design. The participants will be derived from an ongoing birth cohort study, Wheezing Illnesses Study Leidsche Rijn (WHISTLER).

## Study burden and risks

There are no risks associated with participation in this study. There is no benefit for the children in participating to this study and participation is completely voluntary.

## Contacts

### Public

Universitair Medisch Centrum Utrecht

Lundlaan 6  
3508 AB Utrecht  
NL

### Scientific

Universitair Medisch Centrum Utrecht

Lundlaan 6  
3508 AB Utrecht  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

- 3 year-old children of the Whistler-cohort

### Exclusion criteria

Children with a history of a heart defect will be excluded from this 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): 28-12-2011

Enrollment: 170

Type: Actual

## Ethics review

Approved WMO

Date: 02-11-2011

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO  
Date: 19-06-2012  
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
CCMO	NL36402.041.11