

# Cardiovascular system in Children with Cystic fibrosis

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We hypothesised that cardiovascular changes already exist in children with cystic fibrosis compared with healthy control children. Therefore, we will evaluate the cardiovascular system in a group of children with cystic fibrosis compared with...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Myocardial disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON37600

### Source

ToetsingOnline

### Brief title

Triple C

### Condition

- Myocardial disorders
- Congenital respiratory tract disorders

### Synonym

CF or mucoviscidosis, Cystic Fibrosis

### 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, Cystic Fibrosis

## Outcome measures

### Primary outcome

The main study parameters are the echocardiographic measurements of the cardiovascular system (diastolic function of the right and left ventricle).

### Secondary outcome

Secondary study outcome is arterial stiffness (pulse wave velocity) and the respiratory system (the lung function measurement).

## Study description

### Background summary

The life-expectancy of patients with cystic fibrosis is increasing and the proportion of patients with cystic fibrosis who are middle-aged is increasing. Therefore, there is a need to focus on extra-pulmonary comorbidities that affect the length and quality of life in the adult stage of the disease.<sup>1</sup>

Several studies showed that adult patients with cystic fibrosis have a decreased systolic and diastolic function of the heart (especially the right ventricle) and an increased arterial stiffness compared to healthy controls. It is unknown when these changes appear.

By our knowledge, the cardiovascular system has not been studied in children with cystic fibrosis. It is important with regard to prevention of cardiovascular disease in cystic fibrosis patients to get a better understanding of the development of this process. If cardiovascular changes already exist in early childhood, it could lead to an earlier screening for cardiovascular disease in these patients.

### Study objective

We hypothesised that cardiovascular changes already exist in children with cystic fibrosis compared with healthy control children. Therefore, we will evaluate the cardiovascular system in a group of children with cystic fibrosis compared with control subjects.

## Study design

Cross-sectional design

## 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  
Utrecht 3508 AB  
NL

### Scientific

Universitair Medisch Centrum Utrecht

Lundlaan 6  
Utrecht 3508 AB  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

Children with cystic fibrosis:

- Aged 3-12 years
- Who visit the pediatric pulmonology department for their regular control visit;Healthy controls
- Aged 3-12 year
- Participating in the WHISTLER study

## Exclusion criteria

Children with cystic fibrosis:

- Children with a history of a heart defect will be excluded from this study.;Healthy controls
- Children with a history of a heart defect will be excluded from this study.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2013
Enrollment:	70
Type:	Actual

## Ethics review

Approved WMO	
Date:	17-12-2012
Application type:	First submission

## 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	NL39258.041.12