

# VO2max in healthy children and children with asthma

Published: 05-02-2013

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Compare VO2max between healthy children and children with asthma

|                              |                 |
|------------------------------|-----------------|
| <b>Ethical review</b>        | Not approved    |
| <b>Status</b>                | Will not start  |
| <b>Health condition type</b> | Other condition |
| <b>Study type</b>            | Interventional  |

## Summary

### ID

NL-OMON36883

### Source

ToetsingOnline

### Brief title

VO2max in healthy children and children with asthma

### Condition

- Other condition

### Synonym

endurance, physical exercise

### Health condition

conditieniveau

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medisch Centrum Leeuwarden

**Source(s) of monetary or material Support:** Wetenschapsfonds van het Medisch Centrum Leeuwarden

## Intervention

**Keyword:** asthma, children, VO2max

## Outcome measures

### Primary outcome

VO2max of healthy children compared to that of children with asthma

### Secondary outcome

Correlation of VO2max and cortisol response (NL 37156.000.11).

## Study description

### Background summary

We recently demonstrated that children with asthma have significant lower salivary cortisol levels compared to healthy prepubertal children]. It is unknown whether this finding has clinical relevance. It remains unclear whether the adrenal response is attenuated due to the chronic inflammation or due to the lower endurance of the children with asthma. If the chronic inflammation is the cause what is the effect of treatment with inhaled corticosteroids. In addition, is the lower endurance the effect of their asthma or the effect of an attenuated adrenal response?

### Study objective

Compare VO2max between healthy children and children with asthma

### Study design

Intervention study

### Intervention

Maximal exercise test according to a standardized protocol.  
During the exercise test oxygen uptake will be measured with a breathanalyser  
Pulse and oxygen saturation will be continuously monitored.

### Study burden and risks

We do not expect any additional risk for the children since they all play community sports and are used to performing exercise.

## Contacts

### Public

Medisch Centrum Leeuwarden

Henri Dunantweg 2  
Leeuwarden 8934 AD  
NL

### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

Children who participated in the NL 37156.000.1 study will be asked to participate. The healthy children can be included if they are prepuberal and have no restrictions for performing an exercise test ;The children with asthma can be included if they have stable asthma and have not been treated with systemic steroids in the previous three months and have no restrictions for performing an exercise test (and do not routinely use salbutamol before exercise)

## Exclusion criteria

If informed consent is not given

if exercise tests are contraindicated due to the physical condition or asthma as judged by the paediatrician

if the child does not want to cooperate during the test or wants to stop the test

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Will not start

Enrollment: 40

Type: Anticipated

## Ethics review

Not approved

Date: 05-02-2013

Application type: First submission

Review commission: CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

## 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     | NL42187.000.12 |