

# Mucoviscidosis and Inflammation, Variability through Exercise and Training: Maximal exercise test

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Primary objective: \*What is the effect of an incremental maximal exercise test on inflammation in patients with cystic fibrosis and in healthy people?\*Secondary objectives:- What are the differences in basal immune values between HP and CF patients...

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Respiratory disorders congenital
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON32340

### Source

ToetsingOnline

### Brief title

MOVIT I

### Condition

- Respiratory disorders congenital
- Congenital respiratory tract disorders

### Synonym

Cystic fibrosis, Mucoviscidosis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** o.a. sponsorproject : "Schaatsen voor Lucht"

via NCFS

## Intervention

**Keyword:** Cystic Fibrosis, Exercise test, Inflammation, Physical exercise

## Outcome measures

### Primary outcome

The primary determinant: graded maximal exercise test.

The primary endpoint: exercise induced inflammatory response (EIIR). The EIIR is the difference between pre-exercise immune levels and post-exercise immune levels.

### Secondary outcome

There are no secondary study parameters.

Secondary endpoints:

- Basal immune values (measurement t0).
- Maximal exercise capacity: this will be determined by the following values:  
peak heart rate (HR<sub>peak</sub>; beats/ min), RER, ventilation threshold (L/ min) according to the equivalent method<sup>100</sup>, peak oxygen uptake (VO<sub>2peak</sub>; L/ min)<sup>101</sup>, peak workload (W<sub>peak</sub>; watt)<sup>102</sup>, efficiency ( $\Delta\text{VO}_2/\Delta\text{workload}$ ; L/ min/ watt)<sup>103</sup>, maximal voluntary ventilation (VE<sub>peak</sub>; L/ min), and oxygen saturation decrease (SaO<sub>2</sub>-decrease; %), whole blood lactate (mmol/ mL).
- Exercise intolerance: when the participant has finished the maximal exercise before fully exhaustion. As mentioned in section 6.1.1. ad 1, this can be estimated by HR<sub>peak</sub> and the RER.

- Exercise induced dyspnoea perception and muscle fatigue perception: at the end of each maximal exercise test, participants are asked to score their sense of dyspnoea and muscle effort/ fatigue at peak exercise using Borg scales.<sup>104</sup> scored with the Borg scale (see section F, appendix 2).<sup>104;105</sup>
- Terminating the maximal exercise test prior to reaching voluntary exhaustion.

## Study description

### Background summary

Exercise has been shown to induce a pattern of hormonal and immunologic responses similar to many known clinical physical stressors (e.g. surgery, and sepsis). When healthy people are subjected to a brief bout of exercise, this induces an immune modulation including transient increases in leukocytes, lymphocytes, natural killer cells and cytokines. Changes in levels of different immune parameters followed by exercise have been attributed to changes in the stress hormones, catecholamines and cortisol.

These changes are positive related with exercise intensity: how bigger the intensity, how bigger the response.

Hypothetically, the defence against micro-organisms will be better when the serum concentration of immune cells increase. However, an excessive and/ or sustained inflammatory response can also induce damage to cells and organ systems. Besides this, exercise with a high intensity (e.g. a marathon) can even induce an immune depression.

In contrast to the large number of studies in healthy subjects of the immune response to acute exercise, much less is known concerning the effect of an acute exercise test on the inflammatory response in CF patients.

Exercise is part of the treatment in CF patients, because it has many benefits for CF patients:

- physical fitness increases
- lungfunction is maintained or even increases
- quality of life increases
- Survival increases

Patients with cystic fibrosis (CF) have a chronic inflammatory status. So the question is if the same perceptions will be seen in CF patients in comparison with healthy people as a response to an acute bout of exercise.

Exercise seems to have many beneficial effects, but is this also true for the influence of exercise on the immune system in CF patients? In CF patients

regular exercise might be beneficial for the defense against micro-organisms. But it also may induce a bigger and longer lasting response which can cause tissue damage. And what will be the effect of an acute exercise test on inflammation during a period of an exacerbation? Is it justified to exercise during a period of an exacerbation? In this study we try to give answers to these questions.

## **Study objective**

Primary objective: \*What is the effect of an incremental maximal exercise test on inflammation in patients with cystic fibrosis and in healthy people?\*

Secondary objectives:

- What are the differences in basal immune values between HP and CF patients, and between CF patients in a clinically stable condition and CF patients with an exacerbation?
- What is the difference in maximal exercise capacity between HP and CF patients, and between CF patients with a clinically stable condition and CF patients with an exacerbation?
- What is the difference in breathlessness and muscle fatigue between HP and CF patients, and between CF patients with a clinically stable condition and CF patients with an exacerbation?
- What is the correlation between pulmonary function (disease severity) and the exercise induced inflammation, and between pulmonary function and basal immune values?
- What is the correlation between maximal exercise capacity and the exercise induced inflammation, and between maximal exercise capacity and basal immune values?

## **Study design**

This investigation is an intervention study with a within-subject-design. The purpose of this investigation is to establish the exercise induced inflammatory response (EIIR) in CF patients and in healthy people (HP). The EIIR is the difference between pre-exercise immune levels and post-exercise immune levels.

## **Intervention**

Niet van toepassing

## **Study burden and risks**

Minor CF patients are needed to accomplish this study. CF is a progressive disease and it manifests most of the times at a young age. Older CF patients are most of the times more severe ill and have more damage to their organ systems. More severe lung disease is an extra burden for the participant, when

he or she should participate.

We realise that every investigation and every measurement will be a burden for the participant, especially for children. Though, we think that the investigation is justified. The risks, and side-effects of the investigation will be minimal. The

Possible risks of placement of an i.v. access: phlebitis, bacteraemia, vasovagal collapse

Possible risks of executing a maximal exercise test: decrease of oxygen saturation (especially in CF patients), sense of breathlessness, exercise induced symptoms like pijn, a headache, dizziness, syncope, arrhythmia.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Adolescents (12-15 years)

Adolescents (16-17 years)

## Inclusion criteria

Inclusion criteria which can be applied for the CF patients:

- CF patients diagnosed by clinical features and a positive sweat chloride test with a homozygote \*F508 mutation
  - CF patients in a clinically stable period: clinically stable means clinically stable for at least 4 weeks, since the exacerbation period. This means no use of (extra) oral or intravenous antibiotics for at least 4 weeks
  - CF patients with a doctor\*s diagnosed acute exacerbation: this exacerbation needs treatment in the hospital with intravenous antibiotics.
  - Age: 12 to 18 years old
  - Sex: male and female;
- Inclusion criteria which can be applied for the healthy people:

Healthy adults:

- > 18 years old
- Sex: male and female

Healthy children:

- Age: 12 to 18 years old
- Sex: male and female

## Exclusion criteria

Exclusion criteria which can be applied for the CF patients:

- Subjects with a physical exercise contraindication by a medical specialist
- Subjects with a known contra-indicatory disease for exercise testing: acute or chronic cardiovascular disease, other pulmonary diseases than cystic fibrosis, acute renal disease, acute hepatitis, metabolic disorders, hemorrhagic diseases, orthostatic hypotension 90;91
- Subject with a known disease which can influences the immune system: acute or chronic inflammatory diseases, acute infection\*
- Subjects who used (inhalation) corticosteroids, and/ or immunosuppressive therapy the last month
- Subjects who used extra antibiotics, on top of their prophylactic antibiotic treatment (regular treatment) within 4 weeks prior to the exercise testing.\*
- Subjects who have had a lung transplantation
- Subjects who smoke

\* This exclusion criteria is not applied to CF patients with an exacerbation.;Exclusion criteria with regard to the healthy people:

- Subjects with a physical exercise contraindication by a medical specialist
- Subjects with a known contra-indicatory disease for exercise testing: acute or chronic cardiovascular disease, acute or chronic pulmonary disease, acute renal disease, acute hepatitis, metabolic disorders, hemorrhagic diseases, orthostatic hypotension 90;91
- Subject with a known disease which can influences the immune system: acute or chronic inflammatory diseases, acute infection\*
- Subjects who smoke
- Subjects who used antibiotics, immunosuppressive therapy, and/ or (inhalation)

corticosteroids within one month prior to the exercise testing

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	24
Type:	Anticipated

## Ethics review

Not approved	
Date:	04-03-2008
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	NL19968.000.07