# Skeletal Muscle Metabolism during Rest, Exercise and Recovery in Patients with Cystic Fibrosis and Healthy Controls

Published: 13-05-2011
Last updated: 27-04-2024

To compare the oxygenation and oxidative metabolism in skeletal muscles of patients with CF with healthy controls to provide insight in the metabolism in patients with CF.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Muscle disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON36204

**Source**
ToetsingOnline

**Brief title**
Muscle Metabolism in CF

### Condition

- Muscle disorders
- Congenital respiratory tract disorders

**Synonym**
mucoviscidosis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** verzoek tot co-financiering is ingediend (d.d. 12-04-2011)

## Intervention

**Keyword:** Cystic Fibrosis, muscle metabolism, oxygen delivery, oxygen utilization

## Outcome measures

### Primary outcome

- * time of PCr recovery (31P MRS)

- Resting, exercise and recovery phoscreatine (PCr)(31P MRS)

- Resting, exercise and recovery Inorganic phosphorus (Pi)(31P MRS)

- Resting, exercise and recovery Pi:PCr ratio(31P MRS)

- Resting, exercise and recovery (Adenosine triphosphate) ATP(31P MRS)

- Resting, exercise and recovery ATP:PCr ratio(31P MRS)Change in concentration deoxygenated hemoglobin. (NIRS)

- Change in concentration oxygenated hemoglobin. (NIRS)

- Change in concentration total hemoglobin. (NIRS)

- Change in concentration deoxygenated hemoglobin minus change in concentration oxygenated hemoglobin. (NIRS)

- The T1/2 (s) change in oxygenated hemoglobin in the recovery phase. (NIRS)

### Secondary outcome

- Peak workload (Wpeak)

- Resting and peak oxygen uptake (VO2peak/kg (ml.min-1.kg-1) )

- Resting and peak minute ventilation (VEpeak) (l.min-1)

- Resting and peak respiratory exchange ratio (RER = VCO2/VO2)

- Resting and peak heart rate (HR; bpm)

- Resting and peak SpO2

# Study description

### Background summary

Patients with CF have a reduced exercise tolerance. Studies show an interrelationship between lung function, muscle mass, energy expenditure, (respiratory) muscle function and exercise capacity in patients with CF. Up to date, there is no scientific evidence or consensus whether the muscle dysfunction is caused by an intrinsic abnormality in muscle energy metabolism and/or is hampered due to impaired oxygen delivery to these muscles, which might be mediated by an increased blood flow demand of the respiratory muscles. Therefore, it remains unclear whether the impaired muscle function is limited by oxygen delivery or oxygen utilization. We hypothesise that patients with CF have impaired oxidative metabolism and/or reduced/slowed oxygen delivery to the skeletal muscles compared to healthy controls.

### Study objective

To compare the oxygenation and oxidative metabolism in skeletal muscles of patients with CF with healthy controls to provide insight in the metabolism in patients with CF.

### Study design

This is an case-control study. Ten patients with CF and ten healthy controls will be recruited. In two separate test-sessions, thigh muscles of a population of patients with CF and healthy age-matched controls will be measured during rest, incremental cycling exercise, and recovery with NIRS (first test) and, in another test session on a separate day, with 31P MRS (second test). The ergometer is made of non-ferrous components, based on the prototype developed by Jeneson et al. for in-magnet bicycling exercise testing (Jeneson et al, 2009).
Before the first (NIRS) test, subjects perform a lungfunction test and adipose tissue thickness is measured. Subjects are asked to fill in a daily activities questionnaire and a MRI and maximal exercise test (only in healthy controls) questionnaire two weeks before the first (NIRS) test day.

### Study burden and risks

No burden and risks are reported concerning exercise in a 31 P-MRS scanner or with NIRS. Participation in this study will take 25 minutes to fill in the questionnaires and will cost 2,5 hours in total on the two separate test sessions. Insight in the muscle metabolism from patients with CF will help to aim and institute interventions as exercise training.

# Contacts

**Public**
Universitair Medisch Centrum Utrecht

Lundlaan 6
3584 EA Utrecht
NL
**Scientific**
Universitair Medisch Centrum Utrecht

Lundlaan 6
3584 EA Utrecht
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)

## Inclusion criteria

Patients with CF:
- Ambulant patients with CF
- free from acute pulmonary or gastro-intestinal exacerbation
- from 12 to 18 years
Healthy controls:
- from 12 to 18 years
- free from constraints in performing a maximal exercise test

## Exclusion criteria

Patients with CF:

- Resting oxygen saturation (SpO2)< 94%
- FEV1predicted < 80%
- Ineligible to perform an exercise test
- Not familiar with the Dutch language
- Presence of contra-indications for 31P MRS measurements (assessed by a standardised questionnaire as previously used in METC 08-267/K)
- Participation in DO-IT or having participated less than six months ago in DO-IT (METC 09-114/K);Healthy controls:
- Ineligible to perform a maximal exercise test (assessed by a standardised questionnaire as previously used in METC 10-468)
- Not familiar with the Dutch language
- Presence of contra-indications for 31P MRS measurements (assessed by a standardised questionnaire as previously used in METC 08-267/K)

# 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: | Diagnostic |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 31-08-2011 |
| Enrollment: | 20 |
| Type: | Actual |

# Ethics review

Approved WMO

| | |
|---|---|
| Date: | 13-05-2011 |
| Application type: | First submission |

| | |
|---|---|
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 27-06-2011 |
| 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 | NL35697.041.11 |