# Blood volume changes in skeletal muscle.

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Other |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON24988

**Source**
Nationaal Trial Register

**Health condition**

vascular endothelium dysfunction, dysfunction arteries, skeletal muscle, blood volume changes.

### Sponsors and support

**Primary sponsor:** Máxima Medisch Centrum
**Source(s) of monetary or material Support:** Stichting Vrienden van het Hart Zuidoost-Brabant Stichting Maxima

### Intervention

### Outcome measures

**Primary outcome**

Reproducibility: Difference and agreement (bias and limits of agreement) of changes in blood volume assessed by power Doppler in the vastus lateralis muscle during maximal and submaximal exercise on two separate days.

**Secondary outcome**

Validity:

- Correlation between changes in power Doppler-signal in the musculus vastus lateralis and changes in blood flow in the afferent artery measured with pulsed wave Doppler during exercise.

- Correlation between changes in total hemoglobulin measured with near infrared spectroscopy and changes in Power Doppler-signal during exercise.

# Study description

**Background summary**

Rationale:

One of the factors that influence exercise performance is the ability to augment blood flow to skeletal muscles during exercise. Therefore, assessment of blood flow changes in exercising muscles may provide important information on physiological limitations of exercise capacity in individual subjects (e.g. athletes, chronic disease). As such, Power Doppler (PD) is a technique capable of measuring changes in fractional moving blood volume (FMBV) and may therefore be useful to assess changes in skeletal muscle blood flow. However, before PD can be used in every day clinical practice, it is important to investigate the day-to-day reproducibility and to validate the PD signal with proven techniques.

Objective:

To investigate day-to-day reproducibility and validity of PD for assessment of skeletal muscle blood flow during exercise.

Study design:

Prospective observational study without invasive measurements.

Study population:

Healthy volunteers between age 18 to 50.

Main study parameters/endpoints:

Reproducibility:

Difference and agreement (bias and limits of agreement) of changes in blood volume assessed by PD in the vastus lateralis muscle during maximal and submaximal exercise on two separate days.

Secondary study parameters/endpoints:

Validity:

- Correlation between changes in PD-signal in the vastus lateralis muscle and changes in blood flow (BF) in the afferent artery measured with pulsed wave Doppler (PWD) during exercise

- Correlation between changes in total hemoglobulin (tHb) measured with near infrared spectroscopy (NIRS) and changes in PD-signal during exercise

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
No adverse effects of submaximal cycling exercise performed by healthy subjects have been reported in literature, nor in our clinical experience. PD, NIRS and PWD are non-invasive measurements and therefore place no additional burden on the subjects. In order to set intensity for the submaximal exercise test, all subjects perform a maximal cardiopulmonary exercise test at baseline. With the inclusion of electrocardiographic analysis and blood pressure measurements during this exercise test, subjects with myocardial ischaemia and ventricular arrhythmias can be identified and excluded.

By performing these measurements, we will be able to evaluate the reproducibility and validity of PD. This study will provide knowledge on the applicability of PD in routine clinical assessment, and eventually, might contribute to a more individualized exercise prescription or therapy.

**Study objective**

One of the factors that influence exercise performance is the ability to augment blood flow to skeletal muscles during exercise. Therefore, assessment of blood flow changes in exercising muscles may provide important information on physiological limitations of exercise capacity in individual subjects (e.g. athletes, chronic disease). As such, Power Doppler (PD) is a technique capable of measuring changes in moving blood volume and may therefore be useful to assess changes in skeletal muscle perfusion. However, before PD can be used in every clinical practice, it is important to investigate the day-to-day reproducibility and to validate the PD signal with proven techniques.

**Study design**

1. Baseline assessment

2. Maximal & submaximal exercise test 1

3. Maximal & submaximal exercise test 2

4. Leg extension test

**Intervention**

The study is designed as a prospective observational study without invasive measurements on healthy subjects. After informed consent is obtained a baseline assessment will be performed. This assessment consists of a physical examination, a questionnaire and an incremental maximal exercise test with respiratory gas analysis. The second assessment consists of a submaximal and maximal exercise test with power Doppler and Near infrared spectroscopy measurement on the vastus lateralis muscle on two separate days. The final assessment consists of an incremental leg extension test with power Doppler measurement on the vastus lateralis muscle and simultaneously a pulse wave Doppler ultrasound measurement on the afferent vessel of the same muscle.

# Contacts

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# Eligibility criteria

## Inclusion criteria

Written informed consent Age 18-50 years. Able to perform a maximal exercise test.

## Exclusion criteria

Subjects with risk of adverse events according to abnormal findings in physical examination or the Lausanne questionnaire. Orthopaedic,cardio-vascular, pulmonary, neuromuscular and other diseases limiting exercise capacity.

# Study design

## Design

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|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Other |
| Start date (anticipated): | 06-12-2015 |
| Enrollment: | 30 |
| Type: | Unknown |

# Ethics review

Positive opinion

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|---|---|
| Date: | 16-11-2015 |

Application type: First submission

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 42467
Bron: ToetsingOnline
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL5442 |
| NTR-old | NTR5569 |
| CCMO | NL55046.015.15 |
| OMON | NL-OMON42467 |

# Study results