Blood volume changes in skeletal muscle.

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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...

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24988

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: Máxima Medisch Centrum
Overige ondersteuning: Stichting Vrienden van het Hart Zuidoost-Brabant Stichting Maxima

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. Baseline assessment

2. Maximal & submaximal exercise test 1

3. Maximal & submaximal exercise test 2

4. Leg extension test

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	06-12-2015
Aantal proefpersonen:	30
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	16-11-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42467
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten