Blood volume changes in skeletal muscle measured with power Doppler ultrasound during whole body exercise: reproducibility and validity.

Published: 23-12-2015
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To investigate day-to-day reproducibility and validity of PD for assessment of skeletal muscle blood flow during exercise.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42467

Source
ToetsingOnline

Brief title
Blood volume changes in skeletal muscle.

Condition

- Other condition

Synonym
dysfunction arteries, vascular endothelium dysfunction

Health condition

endotheelfunctie arteriën

Research involving
Human

Sponsors and support

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

Intervention

Keyword: blood volume, Exercise, power Doppler ultrasound, skeletal muscle

Outcome measures

Primary outcome

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 outcome

Validity:

- Correlation between changes in PD-signal in the musculus vastus lateralis 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.

Study description

Background summary

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 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 burden and risks

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. For healthy subjects (without a cardiovascular condition) there's a very small risk on getting a ventricular arrhythmia or myocardial ischaemia during a maximal exercise test. With the inclusion of electrocardiographic analysis and blood pressure measurements on day 1 during the maximal 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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2016
Enrollment:	38
Type:	Actual

Ethics review

Approved WMO

Date:	23-12-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24988
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL55046.015.15
OMON	NL-OMON24988

Study results

Date completed:	30-06-2016

Actual enrolment:	34