Effect of body position on the cardiovascular response to exercise

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1) elucidate the role of the postural CO decrease on cerebral hemodynamics, 2) test the influence of posture, ageing and T2DM on the CO-VO2 relationship. Furthermore, 3) we want to determine the shape of the CO-VO2 relationship.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON39700

Source
ToetsingOnline

Brief title
Body position and exercise

Condition

- Heart failures
- Diabetic complications
- Central nervous system vascular disorders

Synonym
diabetes, Type-2-diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Exercise, Physiology, Posture

Outcome measures

Primary outcome

The relationship between CO and cerebral hemodynamics in the supine and upright

position.

Secondary outcome

not applicable

Study description

Background summary

Despite intact cerebral autoregulation, there is a persistent decrease in cerebral blood flow (CBF), CBF velocity (CBFV) and cerebral oxygenation (SaO2) on standing up. We hypothesize that the postural decline in cardiac output (CO) may be a contributing factor. In healthy exercising man, there is a more or less linear relationship between CO and oxygen consumption (VO2) with a ~3 L * min-1 increase in CO for each 1 L * min-1 increase in VO2. It is under debate whether this relationship is influenced by posture or ageing.

Study objective

1) elucidate the role of the postural CO decrease on cerebral hemodynamics, 2) test the influence of posture, ageing and T2DM on the CO-VO2 relationship. Furthermore, 3) we want to determine the shape of the CO-VO2 relationship.

Study design

The study is a cross-over intervention study performed by the Laboratory for Clinical Cardiovascular Physiology (LCCP) in collaboration with the Dpt. of Pulmonary Medicine AMC.
In this study, young, aged and T2DM subjects will follow an exercise protocol in both the supine and upright position. The study consists of an introductory day and two measurement days, each of approximately 2 hours. Total time of participation will be about 6 hours. There will be no follow-up whatsoever. Setting and protocol will be described in detail in section 5 of the protocol

(version 2.0)

Intervention

Incremental cycling exercise with 1-min bouts of constant workload.

Study burden and risks

No risks and benefits are anticipated for the subjects in the study population.
The burden will be two cycling exercise protocols till exhaustion.

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

*BMI < 30
reasonable exercise tolerance
(Type-2-diabetes)
Willing and competent to give written incormed consent

Exclusion criteria

*History of: stroke, anemia or polycythemia, known with significant (> 70%) MCA or carotid artery stenosis, clinical manifestation of heart failure or heart disease, clinical manifestation of pulmonary disease, uncontrolled hypertension (BP >160/100 mmHg), orthostatic hypotension, presence of cardiovascular autonomic neuropathy,poor metabolic control (HbA1c > 9.5%), complications of T2DM.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	02-08-2012
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL41192.018.12