

Comparison of cardiovascular structure and function in physical active subjects with or without myocardial infarction

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To assess cardiovascular structure and function, physical capacity and traditional CVD risk factors in i) physical active subject with MI and ii) physical active subjects without MI.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Myocardial disorders
Study type	Observational non invasive

Summary

ID

NL-OMON37343

Source

ToetsingOnline

Brief title

Myocardial infarction and physical activity

Condition

- Myocardial disorders

Synonym

heart attack, Myocardial infarction

Research involving

Human

Sponsors and support

Primary sponsor: CtrtP Scientific Writing and Consulting

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac, myocardial infarction, physical activity, vasculature

Outcome measures

Primary outcome

Vascular structure and function (conduit artery endothelial function, conduit artery diameter, blood flow, IMT, conduit and resistance artery structure, peak hyperemic blood flow, exercise-induced vasodilation)

Plaque vulnerability by ultrasound and serum biomarkers (hs-CRP, SAA, IL-6, MMP-9, MMP-2, TIMP-1, TIMP-2)

Cardiac structure and function (cardiac mass and dimensions, systolic and diastolic function parameters, left and right ventricle strain rate)

Secondary outcome

Secondary objectives include groups comparisons of physical fitness and traditional risk factors, i.e. cholesterol, lipid profile, HbA1C, insulin sensitivity, blood pressure, and waist circumference.

Two extra blood samples will be drawn and stored for future analyses (if no objection participant), in case relevant CVD genetic candidates become available.

Study description

Background summary

The World Health Organization has reported that since 1990, more people have died worldwide from cardiovascular disease (CVD) than any other cause. Previous studies support a strong inverse relationship between the amount of physical activity CVD morbidity and mortality.

While physical inactivity is considered an important independent risk factor for the development of CVD and atherosclerosis and increased physical activity (i.e. exercise) is beneficial in the prevention and treatment of CVD, the mechanisms that underlie the beneficial effects of physical activity are still largely unknown. It appears that only ~60% of the beneficial effects of exercise could be attributed to favourable changes in traditional risk factors such as lipids, cholesterol, high blood pressure, etc. Plausible proposed mechanisms for exercise-induced coronary heart disease protection include improved endothelial function, attenuated plaque progression, stabilization of vulnerable plaques, infarct sparing due to myocardial preconditioning, correction of autonomic imbalance, reduction in myocardial oxygen demand, decreased thrombosis, enhanced collateralization, and decreased inflammatory mediator release. Although physical exercise seems to be a powerful preventive tool for CVD, it is known that CVD and myocardial infarction (MI) occur in physically active populations. Interestingly, post-mortem studies from the 1960s do not reveal any association between coronary atherosclerosis and different levels of physical activity.

To further enhance the knowledge on potential underlying mechanism of CVD and the role of physical activity level, the main objective of this proposal is to compare cardiovascular structure and function in habitual physical active subjects with or without MI.

Study objective

To assess cardiovascular structure and function, physical capacity and traditional CVD risk factors in i) physical active subject with MI and ii) physical active subjects without MI.

Study design

Exploratory Observational study

Study burden and risks

Noninvasive vascular and cardiac testing procedures in this study are not related to any potential risk for the participant. Headache and dizziness of short duration may occur following nitroglycerin spray. Although inflation of the blood pressure cuff during the vascular measurements may induce a slight uncomfortable sensation, this is brief (5 minutes) and stops when the cuff is deflated. A possible complication of venipuncture is a hematoma, which is

induced in ~5% of all cases. To prevent complications, the blood withdrawal will be performed by an experienced professional and sufficient pressure will be provided after withdrawal of the needle.

At the department of Physiology, we have a long-standing tradition in performing the non-invasive testing as used in this present study, i.e. exercise test, cardiac and vascular function and structure measurements. All procedures are performed routinely at the Department of Physiology and have been accepted by the ethics committee in numerous previous applications in healthy as well as various patients groups. Maximal cycling tests will be performed at the hospital under supervision of highly qualified personnel. Participants may experience benefits upon participation, as they will obtain extensive information on their cardiovascular health and physical fitness status.

Findings of this study will contribute to further enhance our understanding on potential underlying mechanism of CVD and the role of physical activity.

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

Informed consent
Men and women aged 40-70 years
For active groups, regular physical active (i.e. aerobic exercise such as running ≥ 3 times a week), for at least 20 years
For MI groups, myocardial infarction within the past 5 years

Exclusion criteria

Smokers
Type I or II diabetes mellitus
Other diseases that interfere with exercise testing
For subject in non-MI groups:
- hypercholesterolemia
- hypertension

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:	Basic science

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	18-04-2012
Enrollment:	40

Type: Actual

Ethics review

Approved WMO	
Date:	10-04-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	24-06-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	22-01-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	21-12-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL38815.091.11