Measuring Athletes* Risk of Cardiovascular Events - Exercise-Induced Cardiac Troponin Release and Coronary Atherosclerosis in Amateur Athletes

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON49634

Source
ToetsingOnline

Brief title
MARC-EXERSCIENCE

Condition

- Coronary artery disorders

Synonym
coronary artery disease, Coronary atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

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

Intervention

Keyword: Athletes, Biomarkers, Coronary artery disease, Troponin

Outcome measures

Primary outcome

The primary outcome is cardiac troponin concentration at 0/30/60/120 and 180 minutes after exercise cessation.

Secondary outcome

Secondary endpoints are other cardiac biomarkers (B-type natriuretic peptide, soluble ST-2, cardiac myosin-binding protein C and Galectin-3) collected at the same timepoints. Furthermore, exercise-specific physiological parameters (including blood pressure, saturation and heart rate), biochemical biomarkers (calcium, parathyroid hormone, phosphate and magnesium) and measures of vascular function (Carotid Artery Reactivity test) are collected to gain more insight into the potential underlying mechanisms of accelerated coronary atherosclerosis in amateur athletes.

Study description

Background summary

Presence of coronary atherosclerosis is associated with an increased cardiovascular risk. An increased prevalence and severity of coronary atherosclerosis is reported among athletes compared to less active controls, suggesting an exercise-dose dependent relationship. Nevertheless, athletes were asymptomatic and had no abnormalities on sports medical examination. Recent studies have reported that post-exercise troponin concentrations above the 99th percentile are predictive of adverse cardiovascular outcomes. High post-exercise troponin concentrations may therefore be indicative of

subclinical cardiovascular disease, such as coronary atherosclerosis. No studies have been performed to investigate this association. We hypothesize that athletes with the most severe coronary atherosclerosis show an exaggerated exercise-induced cardiac biomarker elevation compared to athletes without coronary atherosclerosis. This could possibly imply a novel screening instrument for coronary atherosclerosis.

Study objective

The primary aim of this explorative study is to compare exercise-induced cardiac troponin elevations between athletes with different levels of coronary atherosclerosis. The secondary aim is to compare exercise responses to other cardiac biomarkers across subgroups, whereas physiological and biochemical responses are assessed to gain more insight in the potential underlying mechanisms of accelerated coronary atherosclerosis in amateur athletes.

Study design

An observational cohort explorative study

Study burden and risks

Participants will visit the Radboudumc once for an exercise test on a stationary bike. The burden of the exercise test is low, since all participants are amateur athletes and accustomed to regular exercise training. For safety reasons, a physician will be present during the exercise test. The test can be aborted when termination criteria are met or if the participants decide so (8, 9). Blood will be drawn from an intravenous cannula, which may occasionally (<5%) result in a hematoma. Participants may experience transient pallor, dizziness, weakness or sweating following the blood draw of 20ml per time point (140 ml in total). These symptoms generally disappear rapidly. The carotid artery reactivity test will cause temporal discomfort due to the 3-minute submersion of a hand in ice water, but any discomfort will quickly alleviate after the test and no lasting effects will occur. Taken together, the burden and risks of the present study can be considered as negligible.

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

- Participation in MARC-2 study (so recent information about coronary atherosclerosis is known).
- Availability of recent (<2 years) contrast enhanced coronary CT-scan data
- Willingness to be approached for participation in future research (as indicated on the informed consent form of the MARC-2 study)
- Able to perform a ±1.5 hour exercise test on a bicycle

Exclusion criteria

- Unable to give informed consent
- Presence of a stent in any coronary artery or undergone coronary artery bypass surgery
- Not cleared for exercise training by a cardiologist following the MARC-2 study coronary CT-scan findings
- Absolute contra-indications for an exercise test (as indicated by the Standard Operating Procedure guidelines of the department of Physiology (see page 16 of C1 protocol)).
- Participation in an interventional study targeting cardiovascular health

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2020
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	05-08-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-12-2020
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

ID: 24615
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL74326.091.20
OMON	NL-OMON24615