

Measuring Athlete's Risk of Cardiovascular events

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Primary objective: - To assess the prevalence and severity of coronary artery disease in asymptomatic older (> 45 years) men who undergo exercise testing as part of a sports medical evaluation, with minimally invasive cardiac multidetector...

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

Summary

ID

NL-OMON35520

Source

ToetsingOnline

Brief title

MARC

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

atherosclerosis, coronary artery disease

Research involving

Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum

Source(s) of monetary or material Support: Onderzoeksstichtingen gelieerd aan het Meander Medisch Centrum;nadere financiering wordt gezocht

Intervention

Keyword: athlete, cardiovascular, lifetime physical activity, MDCT

Outcome measures

Primary outcome

- Risk of CV events determined with SCORE.
- MDCT-cardiac imaging data: calcium score (Agatston, volume, mass), presence and severity of coronary artery disease, Total coronary atherosclerotic burden.

Secondary outcome

- Life time physical activity
- Incidental findings on MDCT scanning
- Safety (in particular radiation exposure) and tolerability of MDCT scanning.

Study description

Background summary

Although regular physical activity is the cornerstone of every effort to prevent cardiovascular events, (vigorous) exercise is associated with a transiently increased risk of acute cardiac events, particularly in untrained persons. More than 90% of acute exercise related cardiac events occur in men, predominantly those aged 45 years or over. Acute events in young athletes (aged 35 years or younger) are mainly caused by inherited cardiac diseases, whereas events in older athletes are largely caused by coronary artery disease. Despite the rare occurrence of cardiac events in young athletes (approx. 1 per 100.000 athletes per year) the study group of sport cardiology of the European Society of Cardiology (ESC) recommends mandatory pre-participation screening of athletes aged 35 years or younger. Intuitively, it would make more sense to direct screening efforts at older athletes as they have a higher risk of acute cardiac events. Effectively this would imply screening for the presence of coronary artery disease in (largely) asymptomatic athletes to identify those at a high risk of cardiovascular events. Minimally invasive cardiac imaging is likely to play an important role in this group.

Study objective

Primary objective:

- To assess the prevalence and severity of coronary artery disease in asymptomatic older (> 45 years) men who undergo exercise testing as part of a sports medical evaluation, with minimally invasive cardiac multidetector computed tomography (MDCT) imaging (determining the Agatston score, total coronary atherosclerotic burden and the presence of coronary artery disease - defined as luminal narrowing of at least 50%), irrespective of future cardiovascular disease (CVD) risk as estimated with SCORE and the results of the exercise test.

Secondary objectives:

- To determine the relation between conventional CV risk factors and coronary artery disease (CAD) in this group.
- To determine the relation between lifetime physical activity and CAD in this group.

Study design

The MARC study will be a cross-sectional diagnostic study of 300 asymptomatic men aged 45 years or older undergoing exercise testing as part of a sports medical work-up at Meander Medical Center, Amersfoort, who will be invited to undergo minimally invasive cardiac MDCT imaging. The cardiac MDCT results, combined with the conventional CV risk profile, will be used to provide the participants with a tailored cardiovascular advice, based on the prevailing Dutch guidelines and participants will be followed up for an additional five years to determine the occurrence of hard cardiovascular end-points.

Study burden and risks

For a detailed review of the potential risks, i.e. risks associated with cardiac MDCT, refer to page 12 of the protocol. In brief:

- Adverse reaction to the contrast medium (nausea, skin hives in 1 to 3% of participants, fatal adverse reactions in 0.001%)
- Contrast medium-induced renal insufficiency
- Cancer due to exposure to ionizing radiation (estimated to equal 1 year of background radiation)
- Accidental findings in the scan field may lead to additional diagnostic tests with extra costs and risks not covered by this study.
- Administration of sublingual nitroglycerin prior to CT scanning may cause transient sensations of headache and flushing.
- Administration of metoprolol to lower heart rate prior to CT scanning may cause transient sensations of headache and dizziness. It is expected that only a minority of participants will receive metoprolol to lower heart rate below 70 beats/minute.

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

Male athletes aged 45 years or older age, asymptomatic for heart disease who undergo exercise testing as part of a sports medical evaluation, who are able to understand the study procedure and objectives

Exclusion criteria

Known cardiovascular disease

Rhythm other than sinusrhythm

Pacemaker rhythm

Not able to hold breath for 25 sec.

Asthma/COPD and resting heart rate > 70/min after intravenous administration with beta

blocker)
Iodine-allergy
Hypertension (Blood pressure > 200/110 mmHg)
Obesity BMI >40 kg/m²
Decreased renal function (GFR <60 mL/min)
Language barrier
Unwillingness to be informed about possible incidental findings at CT-scan

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 17-06-2012

Enrollment: 300

Type: Actual

Ethics review

Approved WMO

Date: 20-01-2012

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 08-05-2012

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL38234.100.11