Acute and delayed effects of marathon running on cardiac and skeletal muscle damage

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To assess the effects of marathon running on changes in cardiac and skeletal muscle structure and function using state of the art MRI techniques, ultra-sensitive biomarker assays and a high resolution 64-lead electrocardiogram.

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

Summary

ID

NL-OMON44267

Source ToetsingOnline

Brief title Cardiac and skeletal muscle damage following marathon running

Condition

• Myocardial disorders

Synonym Exercise-induced cardiomyopathy / Cardiac Fatigue

Research involving

Human

Sponsors and support

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

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Intervention

Keyword: cardiac damage, exercise, MRI, skeletal muscle

Outcome measures

Primary outcome

The primary outcome is the MRI characterization of cardiac and skeletal muscle

damage (i.e. edema / diffuse fibrosis / late gadolinium enhancement / etc.).

Secondary outcome

Secondary outcomes include concentrations of cardiac biomarkers (troponin I,

BNP), ECG characteristics and exercise intensity (heart rate) during marathon

running.

Study description

Background summary

Exercise drastically reduces the risk for future cardiovascular events. However, it has been demonstrated that an acute bout of extreme exercise (i.e. marathon) can harm cardiac and skeletal muscle tissue. This is indicated by increased biomarker concentrations for cardiac (troponins) and skeletal muscle tissue (creatinine kinase). An important limitation of previous studies is the lack of sensitive and specific measurements to detect cardiac and skeletal muscle damage. Novel MRI techniques have been developed to allow for more precise characterization of cardiac and skeletal muscle damage and can therefore more accurately depict muscle damage presence, type, location and severity. The combination of imaging data with pre- to post-race changes in ultra-sensitive biomarker assays and high-resolution ECG allow novel insight in the potential detrimental effects of extreme exercise.

Study objective

To assess the effects of marathon running on changes in cardiac and skeletal muscle structure and function using state of the art MRI techniques, ultra-sensitive biomarker assays and a high resolution 64-lead electrocardiogram.

Study design

In this observational pilot study, participants will undergo MRI scans, ECG recordings and blood draws during 5 subsequent study visits (screening, >1 week pre-marathon, <6 hours post-marathon, 24-72 hours post-marathon, *2 weeks post-marathon).

Study burden and risks

The results of this study contribute to the knowledge on the effect of extreme exercise on the heart and skeletal muscle. The risks associated with this study are extremely low. MRI has no associated health risks. MRI does not require ionizing radiation. The MRI protocol does include the administration of a gadolinium contrast bolus, but gadolinium contrast is well tolerated with only very rare cases of gadolinium allergy reported in the literature. To exclude the risk of contrast-induced nephrogenic systemic fibrosis, individuals with a glomerular filtration rate < 30 ml/min will not be included. When patients wish to stop the scanning procedure and get out of the scanner they can press an *alert button*, which is standard procedure for every MRI. Patients are also able to talk to the researchers in the control room at any time during the experiment. The 64-lead ECG has no risks and subjects may only develop a skin rash from the adhesive ECG pads. The blood draws have a small risk (<5%) of causing a local haemorrhage, which is unpleasant but harmless. Patients receive no direct benefits. There is a chance that we will detect coincidental findings on the MRI-scans and these will be discussed with a cardiologist. If further research is necessary than the cardiologist will provide a letter for the general physician of the participant in which the findings are explained and a referral to a specialist (cardiologist/radiologist) is requested to initiate the appropriate care.

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

Marathon runners, >45 years of age, healthy

Exclusion criteria

known cardiovascular diseases, unable to undergo MRI-scan

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):	18-09-2017
Enrollment:	12
Туре:	Actual

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Ethics review

Approved WMO Date: Application type: Review commission:

19-07-2017 First submission 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
ССМО	NL61873.018.17

Study results

Date completed: 18-06-2018

Actual enrolment: 12

Summary results

Trial is onging in other countries