Evaluation of Health Effects of a First Time Marathon in Young Middle-Aged Men

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Investigate the cardiac and non-cardiac changes of first-time marathon training, running and recovery in healthy young men, according to COVID-19 status.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON55255

Source
ToetsingOnline

Brief title
1st MYMAn

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
Cardiovascular Health / Heart conditions

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Indonesia Endowment Fund for Education

Intervention

Keyword: Cardiovascular Health, Health, Marathon, Running

Outcome measures

Primary outcome

Our primary outcome is MRI characterization of cardiac morphological changes and myocardial (mal)adaptation.

Secondary outcome

Secondary outcomes include other cardiac and non-cardiac parameters (training, marathon and recovery related) as seen on echocardiography, CPET, ECG, and changes in biomarkers (CRP, troponin I and T, pro BNP, CK) and fibrosis biomarkers (CT-1 and Galectin-3).

Study description

Background summary

It is well documented that engaging in regular physical activity is associated with numerous health benefits, such as a reduced risk of fatal and non-fatal cardiovascular disease (CVD). However, it is unclear what the upper limits are regarding the beneficial effects of physical exercise on the CV system and general health. Marathon running is currently an activity with pronounced popularity, with predominantly male participants aged 35-50. Correspondingly, this is the age and gender group where a CVD first becomes clinically evident. Adverse events such as sudden cardiac arrest (SCA) and sudden cardiac death (SCD) have been reported among marathon runners, with a 10:1 incidence in men versus women. Marathon runners may also develop deleterious CV effects, such as coronary artery calcification, atrial fibrillation and myocardial fibrosis. Elevations of biomarkers such as myocardial troponins and NT-pro-BNP have also been demonstrated after acute bouts of endurance running, and changes in cardiac structures and function have been shown to persist up to 1 week after a marathon.

No studies have performed a comprehensive longitudinal cardiac evaluation, including a complete battery of state-of-the-art diagnostic modalities and

continuous monitoring, in first-time marathon runners. Furthermore, running a marathon after recovery from COVID-19 has never been investigated. Therefore, we aim to investigate the effects of training for a marathon, performing a marathon, and recovering from a marathon in first-time male runners, on cardiac and non-cardiac indices.

Study objective

Investigate the cardiac and non-cardiac changes of first-time marathon training, running and recovery in healthy young men, according to COVID-19 status.

Study design

A prospective, exploratory cohort study in apparently healthy young middle-aged first-time male marathon runners. Subjects will be observed for 6 months, including the different phases of 1) training; 2) the marathon event itself; 3) recovery. Pre-marathon training will be at the participant's discretion and unsupervised, but with a standard sports advice (progressive self-training for 4 months). Study evaluations comprise repeated CMR, echocardiography, cardiopulmonary exercise testing (CPET), ECGs, blood tests and physical activity reports.

Study burden and risks

The added risks of participation in this study are negligible. However, the risks of marathon running carry a certain level of risk,. However, the marathon running itself is not part of the study protocol, but an individual choice. MRI has negligible health risks. The cardiac MRI protocol does include the administration of gadolinium contrast bolus, but gadolinium contrast is well tolerated with only very rare cases of gadolinium allergy (<0.1%). To exclude the risk of contrast-induced nephrogenic systemic fibrosis, individuals with a glomerular filtration rate < 30 ml/min will not be included. The echocardiogram is a safe, non-invasive procedure using the high-frequency sound waves (ultrasound). CPET, which involves measuring respiratory gases, is considered a safe procedure, especially in healthy adults. The 12-lead ECG has no risks, and subjects may only develop a skin rash from the adhesive ECG pads. The blood collection has a small risk (<5%), causing a local hemorrhage, which is unpleasant but harmless. Patients will be offered a guided training by a licensed coach and a better understanding of the effects of first-time marathon participation from participation in our study.

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

(1) Men aged between 35-50
(2) No known (uncontrolled) medical illness
(3) Has no history of surgery for the past 2 years
(4) Does not suffer from musculoskeletal injury
(5) Has not run or trained for a marathon before
(6) Has not run further than 21.1 km in one single race or training in the last year
(7) Has never trained or competed on a semi-professional or professional level in endurance sports

Subgroup: We aim to include 12 participants (half of the study sample) with a documented covid 19 history (PCR positive) without hospitalization in the past

6 months.

Exclusion criteria

Classified as high risk (symptomatic, or known cardiovascular, pulmonary, renal or metabolic disease) according to ACSM guideline
Contraindications for MRI scanning (claustrophobia or other contra-indication for MRI)
Glomerular filtration rate < 30 ml/min
Illiterate or unable to provide written informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-05-2021
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	26-04-2021
Application type:	First submission
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

ID: 20364
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL70800.029.19
OMON	NL-OMON20364