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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20364

Source
NTR

Brief title
1stMYMAn

Health condition

Healthy first time marathon runners

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: Indonesia Endowment Fund for Education

Intervention

Outcome measures

Primary outcome

MRI characterization of myocardial (mal)adaptation of marathon training and participation as assessed by left and right ventricular end-diastolic and end-systolic volumes (with the corresponding stroke volumes and ejections fractions), mass and wall thickness.

Secondary outcome

· Echocardiography: The functions of cardiac systolic, diastolic, left ventricle, right ventricle, valves and dimensions
· ECG: Detection any ECG abnormalities
· CPET: VO2max
· Heart rate: Exercise intensity, resting heart rate
· Cardiac biomarkers: Troponin I and T, N-T pro BNP, CT-1 and Galectin-3
· Cardiomyocyte integrity: LGE, mean diffusivity (MD), extracellular volume fraction (ECV)

Study description

Background summary

Rationale: 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 a 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.

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 population: 24 healthy men aged 35 – 50 years of age who will participate in a

marathon event for the first time. If possible, half of the participants included will have recovered from COVID-19.

Main study parameters/endpoints: Our primary outcome is MRI characterization of cardiac morphological changes and myocardial (mal)adaptation. 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).
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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

Study objective

What are the health effects of first time running a marathon ?

Study design

1 week

Contacts

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Eligibility criteria

Inclusion criteria

· Men aged between 35-50
· No known (uncontrolled) medical illness
· Has no history of surgery for the past 2 years
· Does not suffer from musculoskeletal injury
· Has not run or trained for a marathon before
· Has not run further than 21.1 km in one single race or training in the last year
· Has never trained or competed on a semi-professional or professional level in endurance sports
· Agree and signed the informed consent to participate in this study

Subgroup: If possible, we will aim to include 12 participants (half of study sample) with a documented covid 19 history (PCR positive) without hospitalization for 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 non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2021
Enrollment:	24
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-03-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55255
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8455
CCMO	NL70800.029.19
OMON	NL-OMON55255

Study results