What is the clinical relevance of exercise induced increases in cardiac troponin levels on survival and cardiovascular incidents?

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Baseline resting levels of cardiac troponin have been shown to be a predictor fur future cardiovascular events and mortality. We hypothesize that the exercise induced increases in cardiac troponins may be a superior predictor for survival and CVD...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21919

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Endurance exercise, cardiac troponins, biomarkers, athletes, walking.

Duurinspanning, cardiaal troponine, biomarkers, sporters, wandelen.

Ondersteuning

Primaire sponsor: Radboud University Medical Centre, Nijmegen, The Netherlands
Overige ondersteuning: Radboud University Medical Centre, Nijmegen, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The survival / mortality status of subjects is checked annually, using national registers.

Toelichting onderzoek

Achtergrond van het onderzoek

Exercise-induced cardiac troponin elevations are frequently observed in athletes. The clinical relevance of this phenomenon is currently unknown. This study aims to determine the predictive capacity of exercise-induced cTn elevations for future cardiovascular events and mortality. Therefore we will include 500 participants in this trial and adopt a 5-year follow-up design. Data regarding the incidence of cardiovascular diseases, cardiovascular incidents and mortality (all-cause and CVD specific) will be collected annually.

Doel van het onderzoek

Baseline resting levels of cardiac troponin have been shown to be a predictor fur future cardiovascular events and mortality. We hypothesize that the exercise induced increases in cardiac troponins may be a superior predictor for survival and CVD events.

Onderzoeksopzet

There will be an annual follow-up regarding the health status of each subject.

Onderzoeksproduct en/of interventie

To study the 5-year predictive power of exercise-induced cTn elevations, I will adopt a semi-prospective follow-up design. Data regarding the incidence of cardiovascular diseases, cardiovascular incidents and mortality (all-cause and CVD specific) will be collected annually. Subjects that successfully completed the first day of the Nijmegen Four Days Marches will be eligible for inclusion. Blood samples are collected pre and post exercise and high sensitivity cardiac troponin I levels are determined accordingly. The incidence of cardiovascular events is scored with the ICD-10 I00-99 classifications using a validated internet based questionnaire (SNAP software). Furthermore, national registers will be used to determine survival/mortality status of participants.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age > 18 years

Participant of the Nijmegen Four Days Marches

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

There are no specific exclusion criteria.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-11-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4027
NTR-old	NTR4295
Ander register	De klinische relevantie van inspanningsgeïnduceerde troponine stijging : TE/CMO/2013/402
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A