Evaluation of Lifetime participation in Intensive Top-level sports and Exercise

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

Summary

ID

NL-OMON55187

Source
ToetsingOnline

Brief title
ELITE cohort

Condition

- Cardiac disorders, signs and symptoms NEC
- Cardiac and vascular disorders congenital

Synonym
cardiomyopathy, heart muscle disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: AMS en NOCNSF

Intervention

Keyword: Athletes, Cardiovascular, Health, Sports

Outcome measures

Primary outcome

The main objective of ELITE is to establish comprehensive cardiac baseline assessment in elite athletes consisting of electrocardiologic characteristics, VO2 max, peak load (in METS or Watt), cardiac biomarkers, lipid profile, ejection fraction (EF), wall thickness of the left and right ventricle, volume of left- and right atria and ventricles, myocardial tissue characteristics including fibrosis using late gadolinium enhancement (LGE), strain of left- and right ventricle, quantification of body composition, and cardiogenetics.

Secondary outcome

na

Study description

Background summary

Sudden cardiac arrest (SCA) is the leading medical cause of death in young athletes.1 While SCA is a rare event, the impact on athletes, their family and surroundings, professionals in sports, and society at large is devastating. Unfortunately, current prevention of SCA in athletes is far from optimal. Limited studies have investigated specific causes of SCA and sudden cardiac death (SCD) in athletes, most studies in sports cardiology are cross-sectional and have used older diagnostic modalities. In addition, little is known about the prognostic implications of possible (minor) abnormalities detected at screening. Furthermore, there is an unmet need to provide advice and specific sports advice in individuals with potentially pathogenic genotypes without signs of specific phenotypes. To answer these questions, prospectively defined cohort studies with extensive baseline data and longitudinal follow-up measurements beyond baseline examinations are needed.2 Therefore, we aim to establish ELITE (Evaluation of Lifetime participation in Intense Top-level

sports and Exercise). With this cohort we investigate the cardiac baselines and effects of intensive top-level sports and exercise, and the development of cardiac pathology.

Study objective

The general objective of ELITE is to establish a cardiac baseline of all NOC*NSF elite athletes, and to investigate changes in cardiac indices over time. The cardiac baseline includes cardiovascular screening using established diagnostic tools, as well as advanced cardiac imaging. Additionally, we aim to establish an elite athlete DNA biobank (for cardiogenetic analyses).

Study design

ELITE is a prospective, longitudinal cohort study and will contain data of the coupled SMART screening. The SMART screening has been established as usual care for all elite athletes according to NOC*NSF and consists of physician consultation, training and injury data (as collected in NOC*NSF athlete management system Smartabase), physical examination, electrocardiogram (ECG), cardiopulmonary exercise test (CPX), laboratory measurements ,transthoracic echocardiogram (TTE) and cardiac magnetic resonance imaging (CMR). In addition to the data collected at the SMART screening, ELITE will include blood for biobanking, to be used for cardiogenetic analyses. After baseline measurements, follow-up is planned at 2-5 year intervals according to age, and at 5-year intervals after cessation of a professional sports career.

Study burden and risks

ELITE is an observational study, collecting data from cardiovascular screenings that are performed as part of usual care (SMART screening) in addition to the ELITE biobank. No adverse or serious adverse events are expected from participation in the cohort, and there is no direct benefit for the participants. Screening results will be treated according to separate screening protocols (usual care). Due to the extensive health examination, potential benefit may be derived from early detection of diseases, as is the objective of the screening.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

>16 years old
Registered as elite athletes according to NOC*NSF (A-status, HP-status or selection status)
Participation in the SMART screening

Exclusion criteria

Unable to give inform consent

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-07-2020
Enrollment:	3000
Type:	Actual

Ethics review

Approved WMO Date:	20-05-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-07-2021
Application type:	Amendment
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: 21171
Source: NTR

Title:

In other registers

Register	ID
CCMO	NL71682.018.19
OMON	NL-OMON21171