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

No registrations found.

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

Summary

ID

NL-OMON21171

Source
NTR

Brief title
ELITE

Health condition

- SCA/SCD
- CMP
- Arrhytmias
- Congenital-, familiar-, and genetical- cardiovascular diseases.

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: Amsterdam Movement Sciences (AMS) & Dutch Olympic Committee * Dutch Sports Federation (NOC*NSF)

Intervention

Outcome measures

Primary outcome

1. To establish a cardiac baseline of all elite athletes(national-, international level, or

NOC*NSF status athletes).
2. To investigate changes in cardiac indices over time in all elite athletes engaging in intense physical activity.

Secondary outcome

3. To establish an elite athlete biobank to investigate genetic profiles and their association with cardiac indices
4. To quantify and investigate the prevalence and clinical consequences of myocardial involvement after COVID-19 in elite athletes (COMMIT).
Tertiary outcome:
5. To compare levels of antibody and T-cell responses to SARS-CoV-2 of athletes with those of mild and severe symptomatic patients with laboratory-confirmed SARS-CoV-2 infection (collaboration with RECoVERED study)

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. Second, the interaction between SARS-CoV-2 infection, sports and the cardiovascular system is largely unknown. It is unclear how SARS-CoV-2-specific immune responses are induced and what role the innate and adaptive immune systems play in clearance of the virus and disease severity. Furthermore it is unknown if and how lasting protective immune response are induced and how the latter affect re-infection risk. In addition, mid and long-term sequelae and their determinants are not all known, particularly in the context of intensive physical exercise/ training.

The general objective of ELITE is to establish a cardiac baseline of all elite athletes (international-, national level and NOC*NSF status 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. We also aim to establish

an elite athlete DNA biobank (for cardiogenetic analyses). We additionally aim to conduct a longitudinal cohort study on post-SARS-CoV-2 athletes. We aim to investigate potential COVID-19 cardiac sequelae, SARS-CoV-2-specific antibody levels and SARS-CoV-2-specific T cell responses in relation to disease severity, clinical recovery or re-infection over time in (extreme) physically active individuals (athletes).
The collaboration of COMMIT and the RECoVERED cohort study is mandatory to determine whether (extreme) physical activity is associated with sequelae, prognosis and lasting protective SARS-CoV-2-specific immunity (RECoVERED cohort study, NL73759.018.20, METC 2020_086, ZonMw funded).

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 will also be conducted in elite athletes on a national-, and an international level. The periodic SMART screening consists of physician consultation, training and injury data (as collected in the NOC*NSF athlete management system), 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 collection for biobanking (to be used for cardiogenetic analyses), and for COVID-19 serology.Follow-up is planned at 2-5 year intervals according to age, and at 5-year intervals after cessation of a professional sports career. A separate sub-cohort study on athletes with a proven SARS-CoV-2 infection will be established: COvid-19 Myocardial Manifestations in Intensive exercise and Top-level sports (COMMIT). Athletes will be offered a (repeat) CMR, and in case of myocardial involvement, they will be referred to dedicated post-COVID outpatient clinics for structured clinical follow-up, including intensive rhythm monitoring, according to the most recent guidelines. COMMIT will collect data from this clinical follow-up, and simultaneously obtain blood samples at 1,3, 6, 9 and 12 months. After 12 months, only data from clinical cardiac follow-up will be collected yearly up to 5 years.

ELITE will enrol elite athletes including athletes at national-, and international levels, or NOC*NSF status athletes >16 years of age . We estimate that the number of eligible cohort participants will grow by approximately 100 per year, due to new (contracted) elite athletes. The (sub)study population of the COMMIT cohort includes athletes who are diagnosed with a SARS-CoV-2 infection (according to standard diagnostic protocols).

The main objective of ELITE is to establish comprehensive cardiac baseline assessment in elite athletes consisting of electrocardiographic characteristics, VO2 max, peak load (in METS or Watt), arrhythmias, cardiac biomarkers, lipid profile, ejection fraction (EF), myocardial wall thickness of the left and right ventricle, volume of left- and right atria and ventricles, myocardial tissue characteristics including fibrosis and oedema using late gadolinium enhancement (LGE), mechanical quantification of body composition, and cardiogenetics. The main endpoint of (sub)study COMMIT are COVID-19 serology and cardiac sequelae, SARS-CoV-2 antibodies, and SARS-CoV-2 specific B-and T-cell responses.

ELITE is an prospective observational study, collecting data from cardiovascular screenings that are performed as part of usual care or offered to elite athletes at national-, or international level (SMART screening and NOC*NSF athlete management system) in addition

to the ELITE biobank, and SARS-CoV-2 immunology. 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. Regarding group relatedness, the sampling is considered to be necessary since it is the only approach to accurately investigate SARS-CoV-2 (re-) infection determinants and outcomes. This will help understand risk of reinfection and disease progression for athletes and contribute to future guidelines and protocols aimed at preventing spread, reducing severity of illness, and return to play.

Study objective

ELITE will provide prospective follow-up over time of cardiac adaptations in elite athletes during their sports career and after cessation, potential COVID-19 cardiac involvement, and viro-immulogic basis of SARS-CoV-2 infection. We therefore aim to investigate the cardiac effects of intensive top-level sports and exercise, cardiovascular adaptation and the development of cardiac pathology in elite athletes.

Study design

We aimed to provide follow-up based on clinical findings.

Intervention

None

Contacts

Public
Amsterdam UMC
Juliette van Hattum

0205668188
Scientific
Amsterdam UMC
Juliette van Hattum

0205668188

Eligibility criteria

Inclusion criteria

- Aged 16 years and older
- Elite athlete (national-, or international level, and/or status athlete according to NOC*NSF)
- Participation in the SMART screening
COMMIT (sub-study)
- Tested positive for SARS-CoV-2 with RT-PCR (or according to other standard diagnostic protocols)

Exclusion criteria

- Unable to give 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):	01-05-2020
Enrollment:	3200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
On request

Ethics review

Positive opinion

Date:	09-03-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55187
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9328
CCMO	NL71682.018.19
OMON	NL-OMON55187

Study results

Summary results
None.