COVID-19 in professional soccer players (COPROS study)

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20328

Source
NTR

Brief title
COPROS

Health condition

COVID-19

Sponsors and support

Primary sponsor: KNVB
Source(s) of monetary or material Support: KNVB and BVO's

Intervention

Outcome measures

Primary outcome

• To determine the cumulative incidence of SARS-CoV-2 (re)infection, measured by semi-quantitative real-time reverse transcriptase PCR (sqRT-PCR) in PSPs with self-reported symptoms suspected for COVID-19 during follow-up.

Secondary outcome

• To determine the cumulative incidence and duration of hospital admission during follow-up.
• To determine the cumulative incidence of death during follow-up.
• To determine the genetic relatedness of SARS-CoV-2 in PSPs with an epidemiological link.

Study description

Background summary

Rationale: Since December 2019, the world has been in the grip of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the disease it causes, coronavirus disease 2019 (COVID-19). Effective management of this pandemic requires estimation of the burden of disease. Currently available literature on COVID-19 mostly represents severe cases admitted to the hospital; data on mild and unsuspected clinical presentations and asymptomatic infections are largely unknown. In professional soccer direct physical contact is part of daily activities. It is unknown whether this is associated with an increased rate of transmission. To determine if there is excessive risk to professional soccer players we propose an observational study.
Objective: Primary objective: to determine the cumulative incidence of SARS-CoV-2 (re)infection, measured by semi-quantitative real-time reverse transcriptase PCR (sqRT-PCR) in PSPs with self-reported symptoms suspected for COVID-19 during follow-up; to determine the genetic relatedness of viruses when more than one PSP in a club is affected.
Study design: Cross-sectional study with prospective follow-up.
Study population: PSPs and active staff members employed by one of the participating soccer clubs.
Intervention: Not applicable.
Main study endpoints: Primary endpoint: sqRT-PCR-confirmed SARS-CoV-2 infection, self-reported symptoms suspected for COVID-19, hospital admission, death and genetic relatedness of SARS-CoV-2 RNA of PSPs with an epidemiological link.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participation in this observational study poses a negligible risk and the burden is considered minimal. In case of self-reported symptoms suspected for COVID-19 during the follow-up, a nasopharyngeal/throat swab will be obtained. A retrospective questionnaire will be administered at enrolment and 12 weekly short questionnaires during follow-up. In case of self-reported symptoms suspected for COVID-19, a diary on symptoms will be kept until the resolution of symptoms. There is no direct benefit to subjects, except that individual test results will be made available to the subject during and after the end of the study.

Study objective

Contactsports may increase the risk for transmission of COVID-19

Study design

Baseline 18 may 2020 - 31 may 2020 follow up 3 months last timepoint 31 August 2020

Intervention

none

Contacts

Public
Amphia Hospital Breda
Jan Kluytmans

0765952060
Scientific
Amphia Hospital Breda
Jan Kluytmans

0765952060

Eligibility criteria

Inclusion criteria

A subject who meets all of the following criteria will be eligible to participate in this study:
• PSPs and staff members in one of the participating soccer clubs

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Age below 18 years
• Direct involvement in the design or execution of this study
• Legally incapacitated or unwilling to provide 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):	18-05-2020
Enrollment:	140
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
pseudoanonymized

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8685
Other	MEC-United : W20.108

Study results

Summary results
planned