COVID-19 in professional soccer players (COPROS study)

Gepubliceerd: 10-05-2020 Laatst bijgewerkt: 13-12-2022

Contactsports may increase the risk for transmission of COVID-19

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20328

Bron
NTR

Verkorte titel
COPROS

Aandoening

COVID-19

Ondersteuning

Primaire sponsor: KNVB
Overige ondersteuning: KNVB and BVO's

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Contactsports may increase the risk for transmission of COVID-19

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

Amphia Hospital Breda
Jan Kluytmans

0765952060

Wetenschappelijk

Amphia Hospital Breda
Jan Kluytmans

0765952060

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	18-05-2020
Aantal proefpersonen:	140
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
pseudoanonymized

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8685
Ander register	MEC-United : W20.108

Resultaten

Samenvatting resultaten
planned