

Sero-surveillance SARS-CoV-2

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1. Hospital personnel working in patient care have a higher chance of contracting COVID-19 due to their contact with COVID-19 patients. Alternatively, 2. Hospital personnel working in patient care have a higher chance of contracting COVID-19 due to...

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

Samenvatting

ID

NL-OMON26401

Bron

Nationaal Trial Register

Verkorte titel

S3-study

Aandoening

COVID-19, humane coronaviruses NL63, 229E, OC43, HKU1

Ondersteuning

Primaire sponsor: Amsterdam UMC

Overige ondersteuning: Amsterdam UMC Corona Research Fund

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

prevalence and time to SARS-CoV-2 seroconversion (IgG and/or IgM) compared between groups. We will test for differences between groups (dichotomous & survival data), assuming a 10% minimally relevant difference. If groups are not statistically different we will use non-inferiority analysis methods to test whether the difference between groups is within the non-

inferiority margin of 10%.

Toelichting onderzoek

Achtergrond van het onderzoek

Prospective cohort study using serial testing for SARS-CoV-2 antibodies in hospital personnel. Inclusion was stratified into three groups: an exposed (personnel working with COVID-19 patients), intermediate (personnel working with non-COVID-19 patients), and control group (personnel not working in patient care). Serology tests were accompanied with digital surveys on COVID-19 like complaints and exposure to COVID-19 patients during and outside of work activities. By comparing seroconversion percentages between groups we will be able to elucidate whether hospital personnel caring for patients have an increased risk on contracting COVID-19 compared to the control group. The addition of the intermediate group will differentiate whether this increased risk is caused by caring for COVID-19 patients or through spread among personnel, e.g. due to lack of social distancing when working in patient care. Furthermore, we will test for the presence of non-SARS-CoV-2 coronavirus-antibodies in our cohort and whether this is associated with SARS-CoV-2 seroconversion and COVID-19 disease severity.

Doel van het onderzoek

1. Hospital personnel working in patient care have a higher chance of contracting COVID-19 due to their contact with COVID-19 patients. Alternatively, 2. Hospital personnel working in patient care have a higher chance of contracting COVID-19 due to a lack of social distancing during their work.

Onderzoeksopzet

Measurements will take place every 4 weeks for a total number of at least 4 times (except for the intermediate group which is only measured once, during measurement moment 4). Depending on the development of the pandemic (e.g. second and subsequent waves) additional measurements will be planned.

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

Amsterdam UMC
Jonne Sikkens

0204444444

Wetenschappelijk

Amsterdam UMC
Jonne Sikkens

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Exposed group: nurses & physicians caring for suspected or confirmed current COVID-19 patients on a COVID-19 unit, ICU or emergency ward.

Intermediate group: nurses & physicians caring for patients without suspected or confirmed current COVID-19 (in contrast to the other groups, this group is only measured once)

Control group: hospital personnel not working in patient care

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Age <18 years old.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd

Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 23-03-2020
Aantal proefpersonen: 800
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 19-05-2020
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	NL8645
Ander register	METC VUmc : 2020.154

Resultaten