SARS-CoV-2 immune response in asymptomatic patients

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

Samenvatting

ID

NL-OMON24645

Bron
Nationaal Trial Register

Verkorte titel
SCOUT-2

Aandoening

SARS-CoV-2

Ondersteuning

Primaire sponsor: Amsterdam UMC, location AMC
Overige ondersteuning: Amsterdam UMC, location AMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective is to determine the quantity and quality of antibody and T-cell responses to SARS-CoV-2 in asymptomatic patients who tested positive for SARS-CoV-2 with

RT-PCR prior to interventions.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: It is poorly understood whether asymptomatic patients infected with SARS-CoV-2 develop an effective immune response. A better understanding of this immune response is important, as it relates to theories on the development of group immunity and the spread of SARS-CoV-2 in the general population. According to the revised national Dutch guideline, preoperative screening should be performed in all asymptomatic patients undergoing surgery using SARS-CoV-2 reverse-transcription-polymerase-chain-reaction (RT-PCR). This screening enables us to identify asymptomatic patients who are SARS-CoV-2 positive for further investigation of their immune response.

Objective: To evaluate the presence and levels of SARS-CoV-2 antibodies and SARS-CoV-2 specific T cell responses in asymptomatic patients who tested positive for SARS-CoV-2 with RT-PCR prior to an intervention.

Study design: Multicenter prospective observational cohort study.

Study population: Adult asymptomatic patients, who underwent preprocedural screening and tested positive for SARS-CoV-2 using RT-PCR. For secondary analyses our cohort will be compared to participants of two different ongoing cohort studies, namely a mildly symptomatic cohort of healthcare workers and a mild to severe symptomatic cohort of hospital admitted patients.

Intervention (if applicable): Study related interventions are obtaining of three or four venous blood samples and three short questionnaires by telephone.

Main study parameters/endpoints: The main study parameter is the level of SARS-CoV-2 antibodies and SARS-CoV-2 specific T cell responses in asymptomatic patients who tested positive for SARS-CoV-2 prior to a procedure, measured at least four weeks after positive screening.

Doel van het onderzoek

It is poorly understood whether asymptomatic patients infected with SARS-CoV-2 develop an effective immune response. A better understanding of this immune response is important, as it relates to theories on the development of group immunity and the spread of SARS-CoV-2 in the general population.

Onderzoeksopzet

2 weeks, 4-6 weeks, 3 months, 6 months and 12 months

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Adult (age ≥ 18 years)
- Screened for COVID-19 according to the national guidelines because of a planned surgical or interventional procedure under general anesthesia.
- Tested positive for SARS-CoV-2 with RT-PCR.
- Asymptomatic at the moment of screening: no suspicion for COVID-19 for at least 48 hours prior to screening, based on a standardized questionnaire containing the following complaints: cough, dyspnoea, fever, general malaise, myalgia, headache, extreme fatigue (new onset), throat ache, obstructed/runny nose, loss of smell, loss of taste, abdominal pain, diarrhoea and vomiting.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Not able or willing to give informed consent.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2020
Aantal proefpersonen:	75
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:	11-06-2020
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	NL8733
Ander register	METC AMC : METC 2020_138

Resultaten