SARS-CoV-2 immune response in asymptomatic patients

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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. The secondary objectives are:- To determine...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON50161

Source
ToetsingOnline

Brief title
SCOUT-2 study

Condition

- Viral infectious disorders

Synonym
COVID-19, SARS-CoV-2

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: antibody, coronavirus, COVID-19, immune response

Outcome measures

Primary outcome

Levels of serum antibody response to SARS-CoV-2 and phenotypic and functional characterisation of SARS-CoV-2-specific T cells.

Secondary outcome

- Neutralisation potency, reactivity against different SARS-CoV-2 and other coronavirus proteins and the effector functions of these antibodies (antibody-dependent cellular cytotoxicity and phagocytosis and complement activation).

- IgA antibody levels in saliva.

- Comparison of antibody and B/T-cell response to SARS-CoV-2 in post-symptomatic patients (patients who had symptoms in the two weeks before positive screening), truly asymptomatic patients, pre-symptomatic patients (patients who developed symptoms in the two weeks after positive screening), versus those of mild and severe symptomatic patients (METC study 2020_154 and RECoVERED study, ZonMw funded).

- Effect of age, comorbidity and RT-PCR cycling threshold values (of the screening PCR).

- Development of SARS-COV-2 antibody levels and B/T-cell responses over time (up to one year after positive testing).

Study description

Background summary

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). In the SCOUT-1 study the yield of preoperative screening was evaluated. Additionally, the screening enables us to identify asymptomatic patients who are SARS-CoV-2 positive for further investigation of their immune response.

Study objective

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.

The secondary objectives are:
- To determine the level of serum antibody response to other (seasonal) coronaviruses.
- To evaluate the effect of age, comorbidity and RT-PCR cycling threshold values as predictors for immune responses to SARS-CoV-2.
- To evaluate the development of antibody and T-cell responses over time (up to one year after positive testing).

The tertiairy objective is:
To compare levels of antibody and T-cell responses to SARS-CoV-2 of asymptomatic patients with those of mild and severe symptomatic patients with laboratory-confirmed COVID-19 (collaboration with METC study 2020_154 and RECoVERED study, ZonMw funded).

Study design

Multicenter prospective observational study.

Study burden and risks

Participation in the SCOUT-2 study brings minimal burden and a negligible risk for participants. Patients are exposed to extra peripheral blood sample collection (72ml per study visit, max. 5 visitis). To enhance patients comfort we will obtain the blood samples during a surgical follow-up visit or at home,

if required by the patient. Questionnaires on symptoms will be taken by telephone, which will take a few minutes of the participant*s time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 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.

Exclusion criteria

Not able or willing to give informed consent

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2020
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	25-06-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	07-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL74280.018.20