Evaluation and validation of a novel blood collecting system using a finger prick for SARS-CoV-2 serology.

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

Summary

ID

NL-OMON51045

Source
ToetsingOnline

Brief title
Ser-CoV

Condition

- Viral infectious disorders

Synonym
corona, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Streeklab Haarlem
Source(s) of monetary or material Support: Streeklab Haarlem

Intervention

Keyword: Finger prick, Saliva, SARS-CoV-2, Serology

Outcome measures

Primary outcome

Primary endpoint:

* The clinically functional outcome measure of the Wantai serological tests on capillary blood (serum collected with the Ser-Col device) will be compared with the outcome measures of the Wantai® tests on the venous blood sample for the detection of total (combined IgM and IgG) antibodies against SARS-CoV-2.

Secondary outcome

Secondary endpoints:

* The difference in sensitivity and specificity for the detection of total SARS-CoV-2 antibodies in saliva versus venous and capillary blood.

* Quantitative differences in measured titers of total antibodies against SARS-CoV-2 using the Wantai® assay between the two blood collecting systems, and saliva using a micro-array.

Study description

Background summary

In this study, we want to evaluate and validate the novel blood collecting system Ser-Col, developed for the self-collection of capillary blood by participants with a finger prick, in comparison to venous blood collection for the detection of antibodies against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Moreover, we want to compare SARS-CoV-2 antibody response in saliva versus blood.

Study objective

1. The primary objective is to evaluate whether Ser-Col for SARS-CoV-2 antibody detection is an acceptable alternative for standard venous blood collection.
2. The secondary objective is to compare SARS-CoV-2 antibody detection in (venous and capillary) blood with detection of antibodies in saliva.

Study design

Single center comparative study in the Spaarne Gasthuis, the Netherlands, in which detection of total SARS-CoV-2 antibody levels in both blood collection systems and saliva will be compared. The samples will be collected 6 weeks after the first day of symptom onset to obtain an acceptable antibody yield.

Study burden and risks

The burden of participating in this study is minimal. Blood collection will take place only once and will be performed with a finger prick and venipuncture, which may cause transient mild discomfort and only rarely infection or bleeding. In addition, saliva will be collected. The potential benefits of the finger prick over the venipuncture are the less invasive nature and the fact that people can perform the blood collection themselves at home. Saliva collection is an easy and non-invasive method and will represent no burden. This will make it possible to quickly determine the seroprevalence or SARS-CoV-2 vaccination response in large populations without laborous and invasive methods. Participants will acquire their test results through mail after the study has finished and the results have been analyzed.

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

- Voluntary participants with an age of 18 years or older. He or she must be able to read and understand the informed consent form and to independently perform a capillary blood collection.
- At least 1 PCR confirmed SARS-CoV-2 infection OR a positive result in serology through venous blood collection

Exclusion criteria

- Voluntary participants under 18 years old.
- Absence of PCR confirmed SARS-CoV-2 infection OR patients with a confirmed respiratory infection with a pathogen other than SARS-CoV-2 OR patients with negative test result for SARS-CoV-2 serology in venous blood collection.

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):	27-04-2021
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	25-03-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-06-2021
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	NL76448.029.21