QuantiFERON-SARS-CoV-2: performance of an Interferon-Gamma Release Assay for COVID-19 before and after vaccination against SARS-CoV-2

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

Summary

ID

NL-OMON51150

Source
ToetsingOnline

Brief title
QFN-SARS: T cell responses pre- and post-vaccination

Condition

- Viral infectious disorders

Synonym
corona, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Qiagen Sciences

Source(s) of monetary or material Support: QIAGEN Sciences LLC

Intervention

Keyword: COVID-19, QuantiFERON, SARS-CoV-2, T cell response

Outcome measures

Primary outcome

The main study parameters are

(1) Corona-specific induction of IFN-γ levels in blood cells of unexposed

non-vaccinated subjects, measured by QFN-SARS (Group 1).

(2) Corona-specific induction of IFN-γ levels in blood cells of subjects

without prior exposure to SARS-CoV-2, 14 days to 24 weeks after completion of

vaccination (Group 2).

(3) Antibodies against SARS-CoV-2 before and after vaccination

The study parameters will allow determination of specificity and sensitivity of

QuantiFERON SARS-CoV-2 during vaccination.

Secondary outcome

(3) IFN-γ levels in subjects with prior exposure to SARS-CoV-2 before (Group 3)

and after vaccination (Group 4).

Study description

Background summary

Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) induces a strong immune response leading to activation of B and T cells. In the field of COVID-19 diagnostics, the B cell response is routinely monitored by measuring antibodies against the nucleocapsid protein (NP), the spike protein (S1) or the

receptor-binding domain of the spike protein (RBD). In addition to binding antibodies, neutralizing antibodies are measured in classical virus neutralization tests and, more recently, surrogate virus neutralization tests, such as cPass* (GenScript).
Protection against a new infection, however, is only partly conveyed by antibodies. T cell-mediated responses are important in overcoming infection. In addition, the T cell memory response is essential for long-term protection. QIAGEN is the world-leader in the field of measuring T cell responses against pathogens, with QuantiFERON-TB, an interferon-gamma-release-assay (IGRA) being a broadly used IVD-test for the detection of (latent) tuberculosis (4). QIAGEN has developed a QuantiFERON SARS-CoV-2 test which is currently available for research use.

Study objective

The study is intended to determine the performance of a QuantiFERON SARS-CoV-2 test that QIAGEN will bring to the diagnostic market. The proposed study will contribute to establishing the diagnostic parameters such as specificity, sensitivity and positive and negative predictive value. The study will demonstrate how well the test performs in subjects that have not been exposed to SARS-CoV-2 and are subsequently vaccinated. In addition, the study will explore the same parameters in subjects with a prior infection.

Study design

This is an observational study with 4 defined groups: Group 1 consists of non-vaccinated subjects without prior exposure to SARS-CoV-2; Group 2 consists of non-exposed, vaccinated subjects (14 days - 24 weeks after completion of vaccination); Group 3 consists of non-vaccinated subjects with a prior natural exposure and Group 4 consists of Group 3 participants after vaccination (14 days - 24 weeks after completion of vaccination).

Study burden and risks

The burden to participants consists of 2 visits to a blood collection site, preceded by completion of a short questionnaire on the subject*s clinical history of SARS-CoV-2 infection and vaccination status. Each visit consists of a routine venepuncture during which max 20 mL blood will be collected. Visits can be up to 4 months apart depending on the time of vaccination and the specific vaccination schedule in the Netherlands. Tests performed will be limited to measuring antibodies against SARS-CoV-2 and the IGRA test. Subjects will be recruited in the Oss region, thus reducing the burden of travel.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Group 1:
- no known prior exposure to SARS-CoV-2 (based on PCR, antigen, antibody testing)
- no signs and symptoms associated with COVID-19 in the 4 weeks prior to testing
- no vaccination against corona
Group 2:
- no known prior exposure to SARS-CoV-2 (preferably Group 1 participants)
- fully vaccinated against SARS-CoV-2 (last dose at least 14 days and maximally 24 weeks before testing)
Group 3:
- proven infection with SARS-CoV-2 14 days-24 weeks prior to testing
- no vaccination against corona
Group 4:

- Proven infection with SARS-CoV-2 14 days-16 weeks prior to testing (=Group 3 participants)
- Follow-up test 14 days-24 weeks after completion of vaccination

All groups: 18 year or older
Applicable consent has been given
Preferably willing and able to travel to Oss for testing

Exclusion criteria

- Subject does meet the inclusion criteria.
- Groups 3 and 4 only: Subject has received convalescent plasma or monoclonal antibodies as therapy for COVID-19
- Subject is a transplant recipient (solid organ or cell) or currently on any treatment for cancer.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	23-06-2021
Enrollment:	950
Type:	Actual

Medical products/devices used

Generic name:	QuantiFERON SARS-CoV-2
Registration:	No

Ethics review

Approved WMO Date:	15-06-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	15-07-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-09-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-11-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL77844.028.21