SARS-CoV-2 immune response

Published: 04-05-2020
Last updated: 04-04-2024

To determine B-cel en T-cel immunity im COVID-19 patients

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

Summary

ID

NL-OMON55057

Source
ToetsingOnline

Brief title
SARS-CoV-2 Immune response

Condition

- Viral infectious disorders

Synonym
COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: Stichting Diakonessenhuis en het RIVM

Intervention

Keyword: ELISpot, Immune response, SARS-CoV-2, Serology

Outcome measures

Primary outcome

To determine both T- and B-cell responses in COVID-19 patients.

Secondary outcome

• To determine the capability of the SARS-CoV-2 ELISpot to detect patients with a wide range of clinical manifestations with COVID-19

• To determine the dynamics in T-cell and B-cell response in time in COVID-19 patients

• To determine differences in immune responses in severe, moderate and mild disease

• To relate lineage strain diversity to disease and immune response

• To determine biomarkers linked to development of severe, moderate or mild disease

• To determine factors for (the development) of immunity to COVID-19

Study description

Background summary

Little is known about the development of immunity after COVID-19 infection

Study objective

To determine B-cel en T-cel immunity im COVID-19 patients

Study design

Observational study to determine B- and T-cel responsen against SARS-CoV-2

Study burden and risks

None besides the risc of venapunction

Contacts

Public
Diakonessenhuis Utrecht

Bosboomstraat 1
Utrecht 3582KE
NL
Scientific
Diakonessenhuis Utrecht

Bosboomstraat 1
Utrecht 3582KE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Before and after COVID-19 vaccination

Exclusion criteria

< 18 years old

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-10-2021
Enrollment:	800
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Covid-19 vaccin

Ethics review

Approved WMO Date:	04-05-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-04-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-05-2021
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
EudraCT	EUCTR2021-001202-30-NL
CCMO	NL73618.100.21