Investigating the immune response to COVID-19 vaccination in lung transplantation patients (COVALENT study)

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22289

Source
NTR

Brief title
COVALENT study

Health condition

End stage lung disease

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG)
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

To determine the antibody response of lung transplantation recipients and patients who are

on the waiting list for lung transplantation, to the SARS-CoV-2 vaccine at 28 days, 6 months and 12 months after the second vaccine dose, compared to the immune response of healthy individuals. Healthy individuals are part of the RECOVAC study (METC approved on 23rd December 2020).

Secondary outcome

1) To determine the antibody response of patients who are on the waiting list for lung transplantation, to the SARS-CoV-2 vaccine at 28 days, 6 months and 12 months after the second vaccine dose, or 3 and 6 months after lung transplantation, depending on when the transplantation takes place, to establish if immunity which is generated prior to transplantation, is sustained after lung transplantation.
2) To determine the T-cell immune responses of lung transplantation recipients, and patients on the waiting list for lung transplantation, to the SARS-CoV-2 vaccine, measured by ELIspot and FACS analysis.
3) To assess adverse events to vaccination.

Study description

Background summary

Immune response to COVID-19 vaccination in lung transplantation patients

Study objective

Lung transplantation patients are immunocompromised due to antirejection therapy. The effectivity of the COVID-19 vaccination in this high-risk patient group is completely unknown.

Study design

Screen/vaccination 1, week 4 vaccination 2, vaccination 2+28 days, vaccination 2+6 months, vaccination 2+12 months, Patients who are vaccinated while on the waiting list receive a transplantation: 3 and 6 months from transplantation

Intervention

SARS-CoV-2 vaccine (not study related), blood samples

Contacts

Public

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Eligibility criteria

Inclusion criteria

● All patients should be eligible for COVID-19 vaccination as described by the instructions of the manufacturer.
● Provision of written informed consent
● ≥18 years of age
● Belong to one of the four populations as named in 4.1.

Exclusion criteria

● Contra-indications for vaccination (unrelated to the study)
-History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (e.g., anaphylaxis) to any component of the study intervention(s).
-Pregnancy at the time of the vaccinations
● Exclusion specific to this investigation
-No administration of SARS-CoV-2 vaccine due to any reason
-Active (hematological) malignancy
-Inherited immune deficiency
-Receiving anti-retroviral medication o Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection.
-Waitlist patients with a passed COVID-19 infection.
-Transplantation candidates who do not receive a transplantation within 15 months after receiving the second vaccination dose will remain included as controls. However, sampling will not continue after long
transplantation if the transplant occurs at a later time.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-02-2021
Enrollment:	180
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-06-2021
Application type:	First submission

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
NTR-new	NL9538
Other	METc UMCG : METc 2021/021

Study results