# Investigating the immune response to COVID-19 Vaccination in Lung Transplantation patients (COVALENT study)

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To investigate the humoral and cellular immune response, and the development of immunological memory to the COVID-19 vaccination in lung transplantation patients. To clarify firstly if immunity develops in these patients and secondly, if the immune...

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| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Immune disorders NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON52266

**Source**
ToetsingOnline

**Brief title**
Covalent

### Condition

- Immune disorders NEC
- Viral infectious disorders
- Respiratory tract infections

**Synonym**
lung transplantation

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** studie is op uitnodiging van ZonMW

## Intervention

**Keyword:** COVID-19, immunogenicity, safety, Vaccination

## Outcome measures

### Primary outcome

The primary study parameter is the antibody response to SARS-CoV-2 in immunized individuals with lung transplantation, defined as an increase compared to reference serum, at 28 days, 6 months and 12 months after vaccination.

### Secondary outcome

The secondary study parameters are:

1) To determine if immunity obtained by vaccination on the waiting list is sustained after lung transplantation

2) SARS-CoV-2 specific T-cell response at baseline, at 28 days, and 6 and 12 months after the second vaccination

3) To assess the possible adverse events as a result of vaccination.

4) IFN- * production measured by SARS-CoV-2 Quantiferon test at baseline, 28 days, 6 months and 12 months after the second vaccination.

5) To determine if COVID-19 infections occur in the vaccinated participants, and to look for correlations in the measured antibody and T-cell responses. 6) To investigate if the immune response to vaccination correlates with the degree of immunosuppression, reflected in e.g. medication dosages, trough levels and the Torque Teno Virus (TTV) levels found in the participants.

7) to investigate the safety, side effects and immunogenicity of SARS-CoV-2

vaccination in lung transplant recipients who have had the infection and who

have recovered.

# Study description

### Background summary

Lung transplant recipients are sensitive to respiratory virus infections due to their immunocompromized status. A virus infection can cause direct harm to the lungs, but additionally, damage may be caused by the inflammatory response, which could lead to rejection of the transplanted organ..
The current COVID-19 pandemic is a threat to people with a lung transplant. Patients with progressive lung failure who are on the waiting list for a transplantation are even more at risk of a COVID-19 infection. The severity of the infection could cause such a rapid decline in lung function that transplantation may no longer be an option. Vaccination is therefore the only way of reducing the risk.

The vaccins which have currently been approved in the EU have been shown to be highly effective. From studies it is known that vaccinated individuals have developed efficient immune responses, with development of both antibodies and T-cells.
Unfortunately however, these vaccines have not been tested in lung transplant recipients. From studies investigating other vaccines it is known that these lung transplant recipients have reduced responses to vaccines, as is the case e.g. for the Influenza vaccine.
People who are on the waiting list still have normal immmune responses to vaccination. In this group we don't know if the immunity acquired after vaccination is sustained after transplantation. This is what we intend to investigate.

### Study objective

To investigate the humoral and cellular immune response, and the development of immunological memory to the COVID-19 vaccination in lung transplantation patients. To clarify firstly if immunity develops in these patients and secondly, if the immune response lasts for 1 year.

### Study design

In this observational cohort study, we aim to determine the immune response of

lung transplantation recipients to SARS-CoV-2 vaccination by measuring antibodies and T-cell responses at different time points.
Baseline samples are taken from participants prior to first vaccination, and these participants are sampled at regular intervals, until a year after vaccination. A group of patients who are on the lung transplant waiting list are immunized and followed at regular intervals. Following transplantation, the observation time is extended to six months after transplantation. Patient characteristics, potential side effects of vaccination, lung function and degree of immunosuppression will be collected.
Study participants are going to receive the SARS-CoV-2 vaccine according to the manufacturer*s instructions. This vaccine is part of standard care. At time of inclusion and after baseline samples are taken, participants are going to receive the first vaccine dose which is supplied by the RIVM for the purpose of this study.

**Study burden and risks**

SARS-CoV-2 vaccine candidates have recently been evaluated for authorization by the European Medicines Agency. However, immunosuppressed patients, have been excluded from SARS-CoV-2 vaccination trials so-far. Therefore, a study to assess vaccine efficacy in these specific patient populations is of great importance, also because these patients are at the highest risk for a severe course of COVID-19. We will monitor and report AEs related to SARS-CoV-2 vaccination. Patients will be offered vaccination, regardless whether they will participate in this study or not. Vaccination is therefore not a study related procedure per sé. Study related procedures involve blood withdrawal, and potentially nasopharyngeal sampling. These are not considered a high-risk action, and in many cases this can be combined with routine blood drawings for diagnostic purposes. There is no direct benefit to the study participants. However, this study will provide highly valuable information about effectiveness of COVID-19 vaccination in this highly immunosuppressed population.
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# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

Lung transplant recipients AND patients on witing list for lung trasnplantation
willing to be vaccinated against COVID-19

## Exclusion criteria

History of severe adverse reacton to a vaccine
Waitlist patients with passed COVID-19 infections
active malignancy
Inherited immune deficiency

# Study design

## Design

**Study type:** Observational invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Completed |
| Start date (anticipated): | 23-02-2021 |
| Enrollment: | 180 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | COVID-19 vaccin Moderna |

# Ethics review

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| Approved WMO Date: | 17-02-2021 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 08-11-2021 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 23-05-2022 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# 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 | EUCTR2021-000875-35-NL |
| CCMO | NL76385.042.21 |

# Study results

Date completed: 24-01-2024

Actual enrolment: 180