

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

Gepubliceerd: 15-06-2021 Laatste bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22289

Bron

NTR

Verkorte titel

COVALENT study

Aandoening

End stage lung disease

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG)

Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

Immune response to COVID-19 vaccination in lung transplantation patients

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

University Medical Center Groningen
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0652724271

Wetenschappelijk

University Medical Center Groningen
H.T.G.M. (Thea) Scholtens

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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 or 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.

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	22-02-2021
Aantal proefpersonen:	180
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	15-06-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9538

Register

Ander register

ID

METc UMCG : METc 2021/021

Resultaten