The immune-response and safety of COVID-19 vaccination in patients with chronic kidney disease, on dialysis, or living with a kidney transplant

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To assess the efficacy and safety of vaccination against COVID-19 in patients with CKD4/5, patients on dialysis, and kidney transplant recipients as compared to controls

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON51071

Source
ToetsingOnline

Brief title
The RECOVAC IR study

Condition

- Other condition
- Renal disorders (excl nephropathies)

Synonym
dialysis, kidney insufficiency, kidney transplantation

Health condition

niertransplantatie, nieraandoeningen zowel in- als excl nefropathieen

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: NWO is benaderd

Intervention

Keyword: COVID-19 vaccination, dialysis, kidney insufficiency, kidney transplantation

Outcome measures

Primary outcome

The primary endpoint is the antibody based immune response on day 28 after the second vaccination. Participants will be classified as responders or non-responders. The definition of response will be based on the latest available data from the pivotal studies and will be defined prior to data analyses and the first database lock. We will inform the METC about this definition and add this information to ClinicalTrials.gov. The percentage of responders of each patient cohort will be compared with the percentage responders in the control group.

Secondary outcome

Other secondary endpoints include longevity of the immune response at 6 and 12 months and levels of SARS-CoV-2 specific T and B cell responses. Safety is a secondary endpoint which will be reported in terms of percentage of solicited local and systemic adverse events (AEs)graded according to severity.

Study description

Background summary

COVID-19 is associated with increased morbidity and mortality in kidney transplant recipients (KTR) and patients with chronic kidney disease (CKD). Therefore, potential efficacious SARS-CoV-2 vaccination would be of great clinical importance in these patients. However, SARS-CoV-2 vaccination studies have excluded KTR and patients with CKD so-far.

Study objective

To assess the efficacy and safety of vaccination against COVID-19 in patients with CKD4/5, patients on dialysis, and kidney transplant recipients as compared to controls

Study design

prospective multicenter multicohort study

Study burden and risks

Patients with kidney disease are hit harder by the COVID-19 pandemic than healthy individuals. Participation in this study gives early access to vaccination against COVID-19. For the control group, participation in the trial helps to protect their partners from getting COVID-19, and gives them early access to the vaccine. This study will generate highly valuable information on the ability to mount an effective immune response in this patient group that can guide management of these patients during the pandemic worldwide. Participation in this study requires 5 hospital visits at 4 of which blood will be drawn. Participants have to fill in a questionnaire at baseline. Potentially eligible subjects who decide not to participate in the study will have access to the general Dutch vaccination program.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. All patients should be eligible for COVID-19 vaccination as described by the instructions of the manufacturer.
2. Age of 18 years or older
3. Capable of understanding the purpose and risks of the study, fully informed and given written informed consent (signed informed consent form has been obtained)
4. Either
- CKD4/5, with an eGFR <30 ml/min*1.73m2 by CKD-EPI
- Hemodialysis, or peritoneal dialysis
- Kidney transplant recipient at least 6 weeks after transplantation
- Partner, sibling, or other family member of participating patient with eGFR > 45 ml/min * 1,73 m2

Exclusion criteria

-History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) toany component of the study intervention(s).
-Multi-organ recipients
-Previous or active COVID-19 disease
-Active (haematological) malignancy
-Inherited immune deficiency
-Infection with Human Immunodeficency Virus (HIV)
-Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-02-2021
Enrollment:	850
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	SARS-CoV-2 vaccin

Ethics review

Approved WMO Date:	16-02-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-02-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-02-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO Date:	05-10-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-01-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-07-2022
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	EUCTR2021-000868-30-NL
CCMO	NL76215.042.21