Long term efficacy and safety of SARS-CoV-2 vaccination in patients with chronic kidney disease stage G4-G5, on dialysis or after kidney transplantation. A prospective observational cohort study by the REnal patients COVID-19 VACcination (RECOVAC) consortium

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To assess the efficacy of SARS-CoV-2 vaccination by the incidence of COVID-19 in patients with chronic kidney disease stage G4-G5, on dialysis and patients after kidney transplantation who received SARS-CoV-2 vaccination

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

Summary

ID

NL-OMON50845

Source
ToetsingOnline

Brief title
The LESS CoV-2 study

Condition

- Other condition
- Viral infectious disorders
- Renal disorders (excl nephropathies)

Synonym
dialysis, kidney insufficiency, kidney transplantatie

Health condition

niertransplantatie, nieraandoeningen zowel in- als exclusief nefropathieën

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMw,volgt

Intervention

Keyword: COVID-19, dialysis, kidney transplantation, SARS-CoV-2 vaccination

Outcome measures

Primary outcome

The efficacy of SARS-CoV-2 vaccination determined as the incidence of COVID-19

after vaccination.

Secondary outcome

Safety in all patients:

• Incidence of mortality

• Incidence of adverse events of specific interest as defined by

(inter)national authorities in collaboration with LAREB

• Incidence of a combined endpoint of acute rejection or graft failure in

patients after kidney transplantation

• Incidence of HLA antibodies defined as calculated Panel Reactivity Antibodies

(cPRA) > 5% in patients on the waiting list for their first kidney

transplantation

Efficacy in a subgroup of patients:

• The antibody response against the SARS-CoV-2 Receptor Binding Domain at 28 days after the final SARS-CoV-2 vaccination.

• The durability of antibody based immune response against SARS-CoV-2 Receptor Binding Domain at 6 months compared to 28 days after completion of SARS-CoV-2 vaccination.

Study description

Background summary

COVID-19 is associated with severely increased morbidity and mortality in patients on dialysis or after kidney transplantation. Therefore, effective SARS-CoV-2 vaccination would be of great clinical importance in these patients. However, SARS-CoV-2 vaccination studies have excluded patients on kidney replacement therapy so-far. Literature data indicate that vaccination may be less effective in these patient groups.

Study objective

To assess the efficacy of SARS-CoV-2 vaccination by the incidence of COVID-19 in patients with chronic kidney disease stage G4-G5, on dialysis and patients after kidney transplantation who received SARS-CoV-2 vaccination

Study design

Prospective observational cohort study.

Study burden and risks

Study related procedures will be limited to blood withdrawals via a mailer-based finger prick (in total a maximum of 1 mL). Risks associated with participation in this study will therefore be minimal. Patients will be vaccinated according to routine clinical practice, wheter or not they are participating in this study and all vaccinated patients are eligible for participation in the trial.

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. 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
• eGFR < 30 ml/min/1.73m2 but not on dialysis or with a kidney transplant
• Hemodialysis, or peritoneal dialysis
• Kidney Transplant recipient at least 6 weeks after transplantation

Exclusion criteria

1. 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).
2.Patients who participate in the RECOVAC-IR study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-04-2021
Enrollment:	12000
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Comirnaty
Product type:	Medicine
Brand name:	COVID-19 Vaccine AstraZeneca
Product type:	Medicine
Brand name:	COVID-19 Vaccine Janssen
Product type:	Medicine
Brand name:	COVID-19 Vaccine Moderna

Ethics review

Approved WMO Date:	25-03-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-04-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-12-2021
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	EUCTR2021-001520-18-NL
CCMO	NL76839.042.21
Other	volgt