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COVID-19 vaccine efficacy evaluation in kidney failure patients

Submission date
12/11/2021

Recruitment status
No longer recruiting

Registration date
15/11/2021

Overall study status
Completed

Last Edited
07/12/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Coronavirus disease 2019 (COVID-19) is caused by a novel coronavirus that has resulted in a global pandemic. COVID-19 infection stimulates Human Leukocyte Antigen (HLA) to produce cytokine proteins, which leads to inflammation-causing lung damage. COVID-19 is associated with significant illness and death in patients with End-Stage Kidney Disease (ESKD). However, SARS-CoV-2 vaccination studies excluded patients with severe or uncontrolled medical conditions, such as patients with ESKD. Also, the immune response to either the infection or vaccination can cause the inducement of HLA antibodies.
The aim of this study is to determine the scale of antibody-based immune response 21 days after the first and second dose of the SARS-CoV-2 vaccine in dialysis and renal transplant patients.

Who can participate?
Dialysis or kidney transplant patients who are 18 years or older who have received or refused the SARS-CoV-2 vaccine

What does the study involve?
Patients will be asked to donate samples of blood. Some will be newly obtained blood samples between 5-14 samples, depending on the group. Some blood samples are previously collected and stored samples between 2-4 samples, collected as part of routine care. The existing samples (stored samples) would have been collected if patients have a kidney transplant or are currently or previously on the national kidney transplant list. This study is meant to be convenient to participants with the timing of blood samples required for research around the participants routine clinical monitoring,
• Dialysis patients: Monthly along with routine monthly blood tests.
• Kidney transplant patients: 4 monthly intervals (monthly if logistically possible) along with blood tests required for the clinic visits or other routine blood monitoring (for example, drug levels). Hence the frequency of visits to the hospital is not anticipated to increase.
During the study, the following information will be collected (age, gender, ethnicity), medical history, including details of medical condition and treatment, whether you have had coronavirus infection before, details of vaccination. Information will be collected from medical records from the time patient enters the study for a period of up to 12 months after receiving a vaccination.

What are the possible benefits and risks of participating?
Benefits: There may be no direct benefit to patients from taking part in this study. However, this study will inform if normalisation of life after vaccination is feasible, such as:
• The safety of immunosuppressed kidney transplant patients coming out of shielding.
• Dialysis patients moving between shifts (Monday/Wednesday/Friday and Tuesday/Thursday /Saturday)
• The safety of dialysis and transplant patients to return to work
The information gained from this study may help to improve how patients with kidney failure are vaccinated for coronavirus in the future.
There are no major risks. Having blood taken may cause some discomfort, bleeding or bruising where the needle enters the body and, in rare cases, light-headedness and fainting.

Where is the study run from?
Liverpool University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
March 2021 to October 2022

Who is funding the study?
The study is funded by Roche with a materials only grant

Who is the main contact?
Dr Anirudh Rao
anirudhrao@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Anirudh Rao

ORCID ID
http://orcid.org/0000-0002-3202-2832

Contact details
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP
+44 (0)151 7063702
anirudhrao@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
297083

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 297083, CPMS 49460

Study information

Scientific Title
Sarscov2 immunity Evaluation post-vaccination iN patIentS On Renal replacement therapy

Acronym
SENIOR

Study objectives
1. SARS-CoV-2 vaccination in dialysis patients and kidney transplant recipients will induce an antibody-based immune response.
2. SARS CoV-2 vaccine could induce HLA antibodies (sensitisation) in transplant patients and those on the waiting list for a renal transplant.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/07/2021, Queens Square Research Ethics Committee (HRA NRES Centre Bristol 3rd floor, Block B, Whitefriars Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8061; queensquare.rec@hra.nhs.uk), ref: 21/HRA/1753

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied

COVID-19 (SARS-CoV-2 infection)

Interventions

1. Assessment of immune response
The measurement of SARS-CoV2 specific antibodies will be using the Elecsys AntiSARSCoV2 S assay (Elecsys Anti-SARS-CoV-2 S.09289275500v1.0).

This study is a pragmatic study with the timing of blood samples required for study in the three cohorts centred around the patients routine clinical monitoring, monthly in dialysis patients, and 4 monthly intervals (monthly if logistically possible) for renal transplant patients.

Dialysis patients will have their study samples monthly with their routine monthly blood monitoring on dialysis by nurses. Home dialysis patients will self-obtain the study samples with their routine monthly blood monitoring. Renal transplant patients will have their study samples at 4 monthly intervals (monthly if logistically possible) and blood tests are taken for their clinic visits by the trust phlebotomy service.

Given that the substantial proportion of participants will have had their first dose of the SARS-CoV2 vaccine, this study intends to utilise stored samples (HLA-specific antibodies and Post-Transplant Save Serum) at Liverpool University Hospitals NHS Foundation Trust pathology department(s) / diagnostic archive(s) for the baseline samples.

The study's blood sampling schedule for assessment of immune response in the four cohorts is detailed below.

Cohort 1 Vaccinated dialysis patients on the UK renal transplant waiting list
Blood/serum for antibody to COVID 19 vaccination at baseline (stored sample-transplant listing blood tests), 21 days post 1st dose of the SARS-CoV-2 vaccine (stored sample -transplant listing blood tests), 21 days post 2nd dose of the SARS-CoV-2 vaccine and monthly after that for 1 year from the date of the 2nd SARS-CoV-2 vaccine

Cohort 2 Vaccinated dialysis patients not on the UK renal transplant waiting list
Blood/serum for antibody to COVID 19 vaccination at 21 days post 2nd dose of the SARS-CoV-2 vaccine and monthly after that for 1 year from the date of the 2nd SARS-CoV-2 vaccine

Cohort 3: Vaccinated renal transplant patients
Blood/serum for antibody to COVID 19 vaccination at baseline (stored sample -transplant listing blood tests), 21 days post 1st dose of the SARS-CoV-2 vaccine (stored sample -transplant listing blood tests), 21 days post 2nd dose of the SARS-CoV-2 vaccine, and 4 monthly after that for 1 year (monthly if logistically possible) from the date of the 2nd SARS-CoV-2 vaccine

Cohort 4: Unvaccinated dialysis and renal transplant patients
Will have no blood or serum samples taken.

2. Evaluation of other parameters:
2.1. Incentre haemodialysis dialysis patients (vaccinated and unvaccinated) will have weekly SARS-CoV-2 PCR monitoring as a routine standard of clinical care and not a study intervention as per the current trust's policy.
2.2. Home dialysis and renal transplant patients (vaccinated and unvaccinated) will have COVID-19 PCR, as indicated by symptoms at COVID-19 testing centres. This data will be collected for 12 months after the first vaccine dose.
2.3. HLA-specific antibodies in dialysis patients on the UK renal transplant waiting list and

transplant patients will be assessed for sensitisation by Luminex solid-phase assay (single antigen beads) as a routine standard of clinical care. This is routine and done after a clinically significant event such as infection, blood transfusion, pregnancy or vaccination.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Primary outcome measure
Level of antibody-based immune response measured using the Roche COVID-19 antibody quantitative assay (Elecsys Anti SARS CoV 2 S assay (Elecsys Anti-SARS-CoV-2 S.09289275500v1.0)) on day 21 after the second SARS-CoV-2 vaccine

Secondary outcome measures
1. The longevity of immune response measured using the Roche COVID-19 antibody quantitative assay (Elecsys Anti SARS CoV 2 S assay [Elecsys Anti-SARS-CoV-2 S.09289275500v1.0]), measured monthly in dialysis patients and four monthly intervals (monthly if logistically possible) for renal transplant patients, up to 12 months following the second SARS-CoV-2 vaccine
2. Disease rates measured using COVID-19 polymerase chain reaction (PCR) test, including hospitalisation and mortality measured using patient records at the end of the study
3. HLA sensitisation in dialysis patients on the UK renal transplant waiting list and renal transplant patients measured by Luminex solid-phase assay (single antigen beads) at baseline and day 21 after the second SARS-CoV-2 vaccine

Overall study start date
30/03/2021

Completion date
15/10/2022

Eligibility

Key inclusion criteria
1. Age of 18 years or older
2. Renal Replacement Therapy patients (dialysis and renal transplant) who have received the SARS-CoV-2 vaccine
3. A comparative arm of Renal Replacement Therapy patients (dialysis and renal transplant) who have refused the SARS-CoV-2 vaccine
4. Capable of understanding the purpose and risks of the study, fully informed and given informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
750

Key exclusion criteria
1. Pregnancy or breastfeeding
2. Active (haematological) malignancy
3. Inherited immune deficiency
4. Infection with Human Immunodeficiency Virus (HIV)

Date of first enrolment
02/08/2021

Date of final enrolment
01/02/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Liverpool University Hospital
Liverpool University Hospital NHS Trust
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Aintree University Hospital
Liverpool University Hospital NHS Trust
Lower Ln
Liverpool
United Kingdom
L9 7AL

Sponsor information

Organisation
Royal Liverpool University Hospital

Sponsor details
Prescot Street
Liverpool
England
United Kingdom
L7 8XP
+44 (0)151 706 3702
RGT@RLBUHT.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.rlbuht.nhs.uk/our-hospitals/royal-liverpool-university-hospital/

ROR
https://ror.org/01ycr6b80

Funder(s)

Funder type
Industry

Funder Name
Roche Diagnostics

Alternative Name(s)
Roche Diagnostics Corporation

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan

The results of the study will be published in a high-impact peer-review journal.
The results will also be published in conferences as either poster or oral presentations.

Intention to publish date
01/11/2022

Individual participant data (IPD) sharing plan
Only aggregate data will be reported. Participant data will not be shared or reported. The datasets generated during and/or analysed during the current study are not expected to be made available as ethics permission has not been sought for this and the access to the de-identified data will be only accessible to the research team.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	01/06/2021	15/11/2021	No	Yes
Protocol file	version 2	01/06/2021	15/11/2021	No	No
HRA research summary			28/06/2023	No	No