Sarscov2 immunity Evaluation post-vaccination iN patIentS On Renal Replacement Therapy- SENIOR STUDY

PARTICIPANT INFORMATION SHEET

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We would like to invite you to take part in a research study. Please take the time to read this information sheet carefully. You may discuss it with others if you wish. Take time to decide whether or not you wish to take part. Joining the study is entirely up to you. If you choose not to take part, this will not affect the care you receive.

Thank you for reading this information sheet.

What is the purpose of this study?
This study aims to collect information on the response of the immune system following vaccination for coronavirus (COVID 19) in dialysis and kidney transplant patients. Patients on dialysis and transplant (on immune suppression tablets) have a weakened immune system making it harder to fight off infections.

The coronavirus vaccines have now being rolled out to protect as many people as possible. However, the vaccines have been mainly tested in healthy volunteers rather than individuals with kidney failure to date. We do not know how well patients on dialysis and transplant will respond to the vaccine. It is essential to know if vaccines will help in returning to normal. For example, dialysis patients move across different shifts and renal transplant patients coming out of shielding. It is also important to understand the best way to give vaccines in the future.

Why have I been invited to take part?
You have been invited to take part because you are on dialysis or have received a kidney transplant. You have received either one or both doses of the coronavirus vaccine.

How do I enter the study?
The first step is to decide whether you want to take part in the study. Your doctor or nurse will describe the research and talk through this information sheet with you. This may be in the clinic where you will be given a copy of this information sheet or over the phone after a copy of it has been sent to you in the post or by email. The information sheet is yours to keep. If you choose to enter the study, you will be invited to sign a Consent Form, either in the clinic or at home, to show that you understand what is involved when taking part in this study. If you have any questions about taking part in the study, please be sure to ask your study doctor or research nurse; their details are provided below.

Do I have to take part?
No. Your participation in this study is entirely voluntary. If you consent to participate, you are still free to withdraw from the study at any time without giving a reason. If you decide not to take part, your care will not be affected in any way. For more information, see the section "What will happen if I don't want to carry on with the study?"

What will happen to me if I take part?
You will be asked to donate samples of blood. Some will be newly obtained blood samples between 5-14 samples, depending on the group you belong to (see below). Some blood samples are previously collected and stored samples between 2-4 samples, collected as part of your routine care. The existing samples (stored samples) would have been collected if you have a kidney transplant or 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.**
- **Renal transplant patients: 4 monthly intervals (monthly if logistically possible) along with bloods tests required for the clinic visits or other routine blood monitoring (for example, drug levels) .**

Hence we do not anticipate the frequency of visits to the hospital to increase.

Research samples (new) will be taken at the following time points for each group

Group 1: Dialysis patients on the UK renal transplant waiting list who have received the COVID vaccine

- Blood for antibody to COVID 19 vaccination upon joining the research or 21 days after 1st dose of the COVID vaccine (stored sample)
- Blood for antibody to COVID 19 vaccination 21 days after 2nd dose of the COVID vaccine (5ml).
- Blood for antibody to COVID 19 vaccination monthly after that for 1 year from the date of the 2nd COVID vaccine (5ml*12=60mls)

Group 2: Dialysis patients not on the UK renal transplant waiting list who have received the vaccine

- Blood for antibody to COVID 19 vaccination 21 days after 2nd dose of the COVID vaccine (5ml).
- Blood for antibody to COVID 19 vaccination monthly after that for 1 year from the date of the 2nd COVID vaccine(5ml*12=60mls)

Group 3: Kidney transplant patients who have received the COVID vaccine

- Blood for antibody to COVID 19 vaccination upon joining the research or 21 days after 1st dose of the COVID vaccine (stored sample)
- Blood for antibody to COVID 19 vaccination 21 days after 2nd dose of the COVID vaccine (5ml).
- Blood for antibody to COVID 19 vaccination 1-4 monthly after that for 1 year from the date of the 2nd COVID vaccine (5ml*4/12=20-60mls)

Dialysis patients on the kidney transplant waiting list and kidney transplant patients will also have blood for HLA antibody taken as per the current norm of care (4*10ml=40mls).

Incentre dialysis patients (vaccinated and unvaccinated) will have weekly COVID swabs per the current norm of care and not a study intervention.

During the study, we will also collect information about you (your age, gender, ethnicity), your medical history, including details of your medical condition and treatment, whether you have had coronavirus infection before, details of your vaccination. We will collect some medical information after your vaccination, including coronavirus infection after your vaccination. We will collect this information from your medical records from the time you enter the study for a period of up to 12 months after you receive your vaccination. Research Electronic Data Capture (REDCap) software will be used to obtain data for this research.

Why are transplant antibodies (HLA) measured in this study?
Blood for transplant antibodies (HLA sensitisation) is collected periodically in dialysis patients on the kidney transplant waiting list and kidney transplant patients routinely. This blood test (HLA sensitisation) is also done after a clinically significant event such as infection, blood transfusion, pregnancy or vaccination. The development of HLA antibodies can cause rejection of transplant kidney and longer waiting times on the transplant list. There are treatments available if a high level of transplant antibody develops (HLA-desensitisation) but is rarely required. This study looks at the effect of COVID 19 vaccination to trigger transplant antibody (HLA sensitisation) and if this is of clinical significance.

What will happen to the samples at the end of the study?
Once the samples have been tested for antibody, they will be destroyed and will not be bio-banked.

What will happen if I don't want to carry on with the study?
You are free to withdraw from this study at any time. You do not have to give a reason and your future care will not be affected. Suppose you choose to withdraw from the study. In that case, we will retain and analyse any information or samples we have collected up until you decide to withdraw.
There is an option for follow up data to be collected after withdrawal. If you choose to stop taking part in the study, we would like to continue collecting information about your health from [central NHS records/ your hospital/ your GP]. If you do not want this to happen, tell us, and we will stop.

What are the possible benefits of taking part?
There may be no direct benefit to you from taking part in this study. However, this study will inform if normalisation of life post-vaccination is feasible, such as

- The safety of immunosuppressed renal transplant patients coming out of shielding.
- Dialysis patients to move between shifts (Monday/Wednesday/Friday and Tuesday/Thursday/Saturday).
- 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.

What are the possible risks of taking part?
The blood samples timing in this study is around your routine clinical monitoring, monthly in dialysis patients (monthly bloods), and 4 monthly intervals (monthly if logistically possible) for renal transplant patients. Hence this study will not increase the hospital visits to have the blood samples taken.
Having blood taken may cause some discomfort, bleeding or bruising where the needle enters the body and, in rare cases, light-headedness and fainting.
If you should become distressed by any of the procedures related to the study, please get in touch using the contact details below under "Further information and contact details."

Will I be paid to take part?
Unfortunately, we will not be able to reimburse you for taking part or any travel-related costs.

Will my taking part in the study be kept confidential?
All information collected about you for this study will be subject to the General Data Protection Regulation and the Data Protection Act 2018 and will be kept strictly confidential. The Liverpool University Hospital NHS Foundation Trust is the Sponsor for this study. We will be using information from your medical records to undertake this study and act as the data controller. This means that we are responsible for looking after your information and using it properly. Research Electronic Data Capture (REDCap) software is designed to provide a secure environment so that research teams can collect and store highly sensitive information. The Liverpool University Hospital NHS Foundation Trust and the NHS will keep identifiable information about you for at least 10 years after the study has finished allowing the results of the study to be verified if needed.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

NHS staff may use your name and contact details to contact you about the research study, make sure that relevant information about the study is recorded for your care, and oversee the study's quality.

You can find out more about how we use your information
- at www.hra.nhs.uk/information-about-patients/ and www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team, or
- by sending an email to RGT@RLBUHT.nhs.uk, or
- by ringing us on 0151 706 3702.

Your GP will be informed that you are taking part in the study.

What will happen to the results of the study?
When the study is complete, the results will be published in a medical journal. You will not be identified in any report or publication arising from the study. We will also make a lay summary of the result available and publicise the results via patient groups, social media. Participants will not receive their individual results for study tests undertaken. This study intends to understand the response to the vaccine.

Who has reviewed the study?
An independent Research Ethics Committee has reviewed this research study. Research Ethics Committees review all research to protect participants' safety, rights, well-being, and dignity.

Further information and contact details

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Thank you for reading this. We hope you agree to take part in this study.