Study of Complications predictable by Pretransplant Lower Urinary Tract Symptoms (SCOPE study)

Principal Investigator: Professor David Kingsmore

IRAS ID 367244

Participant Information Sheet

You are being invited to participate in a research study. Before you decide, it is important that you understand why the research is being done and what taking part would involve. Please read this leaflet carefully and feel free to discuss it with family, friends, or your GP. Ask us if there is anything that is not clear to you or if you want more information. Take time to decide whether you wish to take part or not. Thank you for taking the time to read this

Why have I been invited to take part?

You have been invited because you are due to undergo a kidney transplant at Queen Elizabeth University Hospital, Glasgow. We plan to include around 200 adults receiving kidney transplant in this study.

What is the purpose of the study?

The aim of the study is to allow us to better understand whether bladder problems before transplant are linked with bladder complications for example poor drainage of urine (bladder obstruction) or urine infections after transplant. Urinary problems are the most common problem to occur after transplant. However, currently there is no guidance on what we should be doing to try and prevent these. We hope that by gaining a better understanding of how the bladder works before transplant, we might be able to identify patients at risk of problems prior to their transplant and act to try to prevent this.

Do I have to take part?

No, it is entirely up to you whether you decide to take part or not. If you choose not to participate, your kidney transplant will still proceed in the normal way. Only when you feel satisfied that you have been given enough information about the study and you would like to participate, will you be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. Should you choose not to take part, or to withdraw at a later stage, this will not affect your usual medical care.

What will happen to me if I take part?

If you decide to take part, a member of the research team will meet you at the time you come to your transplant assessment clinic appointment. They will explain the study, answer any questions, and ask you to sign a consent form if you decide to participate

At the transplant assessment clinic (or at another time if it's more convenient to you) a member of the team will meet with you to ask about your bladder function (whether or not your prone to urine infection etc.) You will be also asked to complete a short questionnaire about your bladder function. This takes about 10 minutes.

You will then be asked to pass urine into a special container that measures the stream of urine. Following this a jelly scan (ultrasound) will be performed to ensure your bladder has emptied completely.

If you do not pass urine (generally you need to be able to pass about half a cupful of water), in order to get an accurate result of the flow stream test a small soft plastic tube (catheter) will be inserted into your bladder and a small amount of sterile water used to fill the bladder with water. The catheter will then be removed again and the test repeated.

If any abnormality is found on these tests, you will be referred to a urology doctor (bladder specialist) to check out and make sure your bladder is in the optimal condition for successful transplantation. This will not delay your transplant listing.

Following this appointment, you will be seen by the study team on 4 more occasions: 1 year after your name goes onto the transplant waiting list (if you've not already been transplanted), on the day of transplantation, 6 weeks and 12 months following transplantation. These appointments will be timed to coincide with regular clinic appointments and/ or your routine appointment to have the transplant stent removed. At each of these appointments you'll be asked if you've had any bladder problems, be asked to complete the same questionnaires, urine flow test and bladder scan. The study team will also review your medical records to record any bladder issues/ infections you have needed since your operation.

How many patients are participating in the study?

We aim to recruit approximately 200 patients (100 per group) who are receiving a kidney transplant into the study.

What are the possible benefits of taking part?

It may be that there are no direct benefits to you to taking part. The main aim of the study is so that we can better understand the relationship between pre- transplant unrecognized abnormalities in bladder function and post-transplant problems so that in the future we can improve patient care.

If we were to find an unexpected abnormality on one of your tests, it would not affect you the decision to put your name on the transplant list. This would proceed as normal. However, we would refer to one of our urology team (bladder specialists) to make sure you received the best possible care as soon as possible i.e. an unrecognized problem may be detected sooner than it otherwise might, and potentially preventable problems avoided.

Are there any risks to taking part in the study?

All the tests are tests that are routinely carried out in a urology out-patient clinic. We will not collect any blood or urine samples for research purposes. There is no radiation used in any of the tests and no additional hospital visits will be necessary.

If you do not make urine and require the catheter tube to be inserted, there may be some mild discomfort on catheter insertion. The is a very small risk of introducing infection. This will be minimized by insuring that sterile procedures are followed when inserting the catheter.

Your decision or otherwise to participate in the study will not affect your kidney transplant proceeding in any way.

What will happen to me at the end of the study?

We discharge patients from surgical clinic one year after their transplant. This is routine protocol and will not be changed if you participate in the study.

You will continue to receive all the standard care provided to transplant patients.

I would like to take part. What do I have to do?

If you would like to participate in this study, please contact *David Kingsmore* Tel: *0141 451 6209* or discuss it with your transplant surgeon.

If you decide to participate you will be asked to sign the consent form as proof that you agree to participate in the study. This information sheet and a copy of the signed consent form will be given to you as a record. You should attend your appointments according to the study protocol.

What will happen if I don't want to carry on with the study?

Your participation in this study is strictly voluntary. You have the right to leave this study at any time, just let a member of the transplant team know. If you withdraw from the study we will only use the data collected up to your withdrawal to maintain the integrity of the research. You will not be penalised if you choose to withdraw.

Your study doctor may also decide that you should no longer take part in the study if it is in your best interests or if you do not follow the instructions you receive for taking part in the study.

The Sponsor, Ethics Committee or Regulatory Authority may also decide to stop the study at any time for any reason.

Expenses and payments

There will be no formal payment for volunteering in the study. Wherever possible, study visits will be undertaken while you are on dialysis or to coincide with your regular clinic appointments.

Will my taking part in the study be kept confidential?

Yes. We will be using your information in this study, and the University of Glasgow will act as the data controller. Please see more information about how we use your data in the privacy notice. When we write up and publish this research your input will remain confidential.

What will happen to the results of the research study?

This study is part of a research project for a PhD from the University of Glasgow.

The findings of this study may appear in reports, academic publications, and conference presentations. Once the study is finished, we will display posters that explain the outcome in the different haemodialysis units. If you are unable to see these and wish a copy, please get in touch with the research team.

A fully anonymised version of the data collected from this study will be kept for 10 years and may be used for teaching, further research or audit.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion. Additionally, this study has been reviewed by the University of Glasgow research regulation and compliance team.

Who is funding the research?

The research is funded by the NHS Greater Glasgow & Clyde Renal Unit Endowment Fund. There is no commercial funding.

What will we do with your data?

The University of Glasgow is the sponsor of this research and is responsible for looking after your information. We will act as the data controller for this study We will need to use information from this research project.

This information will include your:

- Name
- Contact details including phone number
- Health data

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of Glasgow will keep identifiable information about you for up to 6 months after the end of the study and your anonymised data for a maximum of 10 years. If you consent to it, your anonymised data may be used in future ethically approved research – this is optional.

Your data will not be shared outside the UK. You can find out more about how we use your information by asking the research team, by visiting www.hra.nhs.uk/patientdataandresearch or send an email to University of Glasgow data protection officer dp@glasgow.ac.uk

Legal basis for processing your data

We must have a legal basis for processing all personal data. As this processing is for Academic Research, we will be relying upon **Task in the Public Interest** in order to process the basic personal data that you provide. For any special categories data collected we will be processing this on the basis that it is **necessary for archiving purposes, scientific or historical research purposes or statistical purposes.**

Alongside this, in order to fulfil our ethical obligations, we will ask for your **Consent** to take part in the study Please see accompanying **Consent Form**.

Who do we share it with?

All the personal data you submit is processed by staff at the University of Glasgow in the United Kingdom. In addition, security measures are in place to ensure that your personal data remains safe: pseudonymisation, secure storage, and encryption of files and devices.

We will provide you with a copy of the study findings and details of any subsequent publications or outputs on request.

What are your rights?

GDPR provides that individuals have certain rights including: to request access to, copies of and rectification or erasure of personal data and to object to processing. In addition, data subjects may also have the right to restrict the processing of the personal data and to data portability. You can request access to the information we process about you at any time.

If at any point you believe that the information we process relating to you is incorrect, you can request to see this information and may in some instances request to have it restricted, corrected, or erased. You may also have the right to object to the processing of data and the right to data portability.

Please note that as we are processing your personal data for research purposes, the ability to exercise these rights may vary as there are potentially applicable research exemptions under the GDPR and the Data Protection Act 2018. For more information on these exemptions, please see UofG Research with personal and special categories of data. If you wish to exercise any of these rights, please submit your request via the webform or contact dp@gla.ac.uk

Complaints

If you wish to raise a complaint on how we have handled your personal data, you can contact the University Data Protection Officer who will investigate the matter.

Our Data Protection Officer can be contacted at dataprotectionofficer@glasgow.ac.uk If you are not satisfied with our response or believe we are not processing your personal data in accordance with the law, you can complain to the Information Commissioner's Office (ICO) https://ico.org.uk/

What if I want to discuss things further?

If you want to discuss things further with a member of the research team, please contact Ms Emma Aitken, Consultant Transplant Surgeon, Queen Elizabeth University Hospital Telephone: 0141 451 6209 Email: emma.aitken10@nhs.scot. If you wish to discuss the study with a member of the transplant team not involved with the study, please contact Mr Andrew Jackson Telephone: 0141 451 6211 Email: Andrew.Jackson2@nhs.scot.

Thank you for taking time to read about and considering participating in the SCOPE study.