



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

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.

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 100 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 drained 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 before your transplant surgery.

They will explain the study, answer any questions, and ask you to sign a consent form if you decide

After you've been admitted to hospital to receive your transplant, a member of the team will meet with you to ask about your bladder function (whether or not you 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.

Irrespective of the findings from the tests, your transplant will proceed as would be standard thereafter. However if anything unexpected is found, this would allow us to do additional tests to check your bladder afterwards.

Following the transplant you will be seen at 6 weeks and 12 months after the transplant. 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 water works problems, be asked to complete the 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 100 patients 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 your transplant. This would proceed as normal. However we would refer you shortly after the transplant 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.

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. There is a very small risk of introducing infection. This will be minimized by insuring that sterile procedures are followed when inserting the catheter. If you don't pass urine, please don't let the need for a catheter put you off participating. If you've not made urine for some time, it is all the more important to check out your bladder function.

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.

What will happen to the results of the study?

The results of this study will be published in scientific journals, presented at medical conferences and made publicly available to try and improve the care of people receiving kidney transplant in future.

Individual people will not be identified, and complete anonymity will be maintained throughout the study and in publication of the results. It is hoped that the results of the study will help us better understand the link between bladder symptoms before transplant and complications occurring after transplant.

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

If you would like to participate in this study, please contact *David Kingmore* 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. 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. All information about your participation in the study will be kept confidential. The information will be held securely and anonymously in electronic format under the provisions of the Data Protection Act 2018 and the General Data Protection Regulation. Your data will be stored in a secure database at the University of Glasgow.

NHS Greater Glasgow and Clyde is the sponsor for this study. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for the study. This means that we are responsible for looking after your information and using it properly. NHS Greater Glasgow and Clyde will keep identifiable information about you for a maximum of 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at <https://www.hra.nhs.uk/information-about-patients>, or by contacting your study team (details below).

Certain individuals from NHS Greater Glasgow and Clyde and regulatory organisations may look at your medical and research records to check the accuracy of the research study. NHS Greater Glasgow and Clyde/ University of Glasgow will only receive information without any identifying details. The people who analyse the information at the University of Glasgow will not be able to identify you and will not be able to find out your name, healthcare record number and contact details.

What if I have a problem?

If you have any concerns regarding your treatment, contact the clinical team who are responsible for your care.

If you have concerns or questions regarding the study, you should ask to speak to the research team at your hospital who will do their best to answer your questions.

If you are unhappy and wish to complain you can do this using the NHS Complaints Procedure. For information on our complaints procedures or advice on how to make a complaint:

- During office hours (9.00am to 5.00pm), telephone **0141 201 4500** (for complaints only). Please listen carefully and pick the right option for the service you want to complain about.
- E-mail: complaints@ggc.scot.nhs.uk

In the event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against the Sponsors or the NHS Trust or Board, but you also may have to pay your legal costs. In the unlikely event that you are harmed from your participation in the study, NHS Greater Glasgow and Clyde maintains clinical trials insurance.

Who is organising the research?

The study is being run by Professor David Kingmore based in NHS Greater Glasgow and Clyde.

The sponsors for this study are NHS Greater Glasgow and Clyde.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This is done to protect your safety, rights, wellbeing and dignity. The study, this Participant Information Sheet, Informed Consent Form and other study documents have been reviewed and given a favourable opinion by the <xxxxxx>

I would like to discuss the study further. Who do I contact for additional information?

You are encouraged to ask any questions that you may have before, during or after treatment. If you have any specific queries about any aspect of this study please ask to speak to the researchers who will do their best to address any questions or concerns. Your local research contact is:

David Kingmore Tel: 0141 451 6209 Email: david.kingmore@ggc.scot.nhs.uk

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