*Sir Charles Gairdner Hospital*

**Participant Information Sheet/Consent Form**

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| --- | --- |
| **Title** | Does early removal of ureteric stent simultaneously with indwelling urethral catheter post kidney transplantation reduce the infection and healthcare costs? |
| **Short Title** | Early removal of the plastic stent |
| **Coordinating Principal Investigator** | Bulang He |
| **Associate Investigator(s)**  | Lingjun Mou, Bryon Jaques, Neil Boudville, Aron Chakera |
| **Location** | SCGH |

**Part 1 What does participation involve?**

1. **Introduction**

You are being invited to take part in this research project because you have end stage renal failure and you are listed for kidney transplantation. The research project is testing a modified procedure of kidney transplantation for early removal of a ureteric stent (a plastic tube inserted to prevent urological complications).

This Participant Information Sheet and Consent Form tell you about the research project. It explains the tests and treatments involved. Knowing what is meant will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part in this study you might want to talk about it with a relative, friend or your doctor.

Participation in this research is voluntary. If you don’t wish to take part, you do not have to. You will still receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section after you have read the information and had a discussion with the medical staff (investigators). By signing it you are telling us that you:

• Understand what you have read

• Agree to take part in the research project

• Agree to the tests and treatments that are described

• Agree to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

1. **What is the purpose of this research?**

The purpose of this research is to investigate a modification to kidney transplant procedure for early removal of ureteric stent after transplant. During kidney transplantation, a plastic stent is placed across the join of the ureter (the tube that drains urine from kidney to bladder) and bladder. Currently, this tube is removed by a procedure involving the insertion of a scope into the bladder (Cystoscopy) and removing the stent. This also involves a day admission to hospital 4-6 weeks after kidney transplantation. Although, it is known that placement of this plastic tube reduces the major surgical complication of urine leak and ureter narrowing, this plastic tube can cause other issues such as urinary tract infection, viral infection, discomfort and sometimes (but rare) it can be forgotten. Usually, this tube is left inside for about 4-6 weeks before removal.

Therefore, the aim of this study is to test a new method of removing this stent earlier. The stent will be put in place as per standard care but will be connected to the urethral catheter (the tube that is put in place to drain urine from the bladder after transplantation) by a fine suture string.

Instead of attending an appointment 4-6 weeks after transplant the stent will be removed 4-5 days after surgery, at the same time as removal of urethral indwelling catheter, before you are discharged home. This method will remove the need for you to undergo the cystoscopy procedure and to avoid a day in hospital to remove the stent 4-6 weeks after discharge.

It is hoped that this will have the benefit of reducing infections related to the stent being left in place, reduce the burden on kidney transplant recipients and will also represent a cost saving to the health care system.

**3 What does participation in this research involve?**

The research project will involve two groups. Firstly, patients like you who are awaiting kidney transplantation will be given this information sheet and asked to take part in this study. Those who consent will undergo the modified procedure for early stent removal. If you do not agree to participate in this study, your surgery for kidney transplantation will be done as usual.

Secondly, information from a group of previous patients who have had kidney transplants according to the standard surgical procedure over the last two years will be collected and compared with the information collected from you to demonstrate if this minor change of procedure is safe and beneficial for kidney transplant recipients.

This information will include rates of surgical complications related to urine leakage, narrowing of the ureter (the tube that connects the bladder and kidney), urinary tract infection rates, kidney graft function (how well the kidney is recovering and performing after transplantation) as well as the cost to the health service associated with the procedure.

This research has been initiated by the study doctor, Professor Bulang He.

This research is being conducted at SCGH.

**4 What will I be asked to do?**

You will be educated about kidney transplant and given the details of the research by investigators in person. If you decide to participate in this study, you will be asked to give written consent for enrolment to the study.

On the day of surgery for kidney transplantation, you will have the study explained again and be asked to consent to the procedure.

As per hospital policy, you will also have kidney transplantation explained again and a surgical consent will be signed by you separately.

During the procedure of kidney transplant a fine suture will be used to connect the stent (the plastic tube that is placed across ureter-bladder joint) to the tip of the urethral catheter. This takes approximately five minutes.

On Day 4 or 5 the urethral catheter will be removed and the stent will be removed at this same time. (Figure 1)



Figure 1

If you take part in this research project, the study doctor will inform your renal physician.

**5 Other important information about the research project**

This study will recruit 80 participants awaiting kidney transplantation and use another 80 recipients who already had kidney transplant by usual technique over last 2 years. Your length of hospital stay and clinical follow up is expected to be the same as those who do not participate in this study.

**6 Do I have to take part in this research project?**

It is important for you to understand that your participation in this study is voluntary. If you do not wish to take part in it, you do not have to. If you decide that you will take part and later change your mind, you are free to withdraw from the study at any stage.

Your decision whether or not to take part in this study will not affect the care you receive or your eligibility to undergo kidney transplantation. Your decision whether to take part or not take part, or take part and then withdraw will not affect your treatment, your relationship with the treating team, or the relationship with Sir Charles Gairdner Hospital in any way.

If you do decide that you will take part, you will again have the details of the study and the procedure explained to you by medical staff (investigators) at the time of surgery. If you change your mind about your decision to take part in this study prior to surgery you are free to do so. This will not affect your ability to undergo surgery.

You will be given this Participant Information and Consent Form to read and sign and you will be given a copy to keep.

**7 What are your alternatives/options to participation?**

The alternative is that you do not have to take part in the study. If so, your kidney transplantation surgery will be done as usual in a standard open surgery. The plastic tube will be placed across the joint of the ureter and the bladder. This plastic tube will be removed by cystoscopy under local anaesthetic 4-6 weeks after transplant. You will need a day admission to the hospital for this procedure

**8 What are the possible benefits of taking part?**

The possible benefits are expected as below:

* To have the ureteric stent (the plastic tube) early removal on day 4-5 post transplantation before discharge
* To reduce the risk of urinary tract infection
* To reduce the discomfort from the stent irritation/soreness
* To reduce the risk of blood in the urine due to stent rubbing against the bladder
* To avoid stent migration or stone formation over the ureteric sent
* To avoid the procedure of cystoscopy and a day admission
* It is cost saving
* We cannot guarantee every individual participant will receive the expected benefits from this study. However, the benefits are expected in general for the future transplant recipients.

**9 What are the possible risks and disadvantages of taking part?**

Currently, this modification to the procedure for stent early removal is still being studied. As such, the differences in risk between this and the standard method for stent removal are not clear. However, recent research has not shown any increased risks of surgical complication by early removal of the ureteric stent. Through our own experience in child kidney transplant recipients, no increased risk of surgical complication was observed over the last 10 years with early removal of ureteric stent.

Generally, as is the nature of kidney transplant procedures, there is a possible risk of developing urine leakage or narrowing of the ureter. The incidence ranges from 3%-10%. However this possibility is not likely to be increased by early removal of the ureteric stent.

If complications occur, an interventional procedure or open surgical procedure may be required to fix it. Rarely, it may result in loss of the transplanted kidney.

**10 What will happen to my information?**

The care you are provided during the period of hospitalization will be the same as the standard of care given to all kidney transplant patients. This includes your clinical follow up plan.

The results of blood and urine tests will be stored on the hospital computer network and your medical record as well any images such as ultrasound scans.

You are not required to have any additional tests for this study. However, you will be monitored after transplantation and if your doctor believes it necessary, you may need more tests or investigations if a problem occurs. As mentioned above, like any surgery the kidney transplantation is associated with some risk of complication and these complications may not be directly linked with the study.

The results of your care and outcomes will be collected and compared with patients undergoing the standard procedure in order to investigate the benefits and risks of changing surgical practice.

If this study is successful, the results may mean clinical practice is changed to improve care for kidney transplant recipients and reduce costs to the health care service.

**11 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project, you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw from the research project. If this happens, the doctor will explain the reasons and arrange your regular health care to continue.

**12 Can the participant have other treatments during this research project?**

You can continue all your medical treatment as needed while you are participating in this study.

**13 What if I withdraw from this research project?**

If you decide to leave the study, please notify a member of the research team before you withdraw. This notice will allow the research supervisor to further discuss any health risks or special requirements linked to withdrawing.

Please be aware, if you wish to withdraw from the study the decision **must** be made before the surgery. Once you have undergone surgery, it is impossible to reverse once completed.

However, if you do withdraw after surgery, the study doctor and relevant study staff will not collect any more information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and comply with law. You should be aware that the data collected will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

**14 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These reasons may include

* Unacceptable surgical complications arising from the study such as increased rate of urine leakage or narrowing the ureter.
* Any other concerns raised during the study

**15 What happens when the research project ends?**

At the end of study, the data will be investigated to identify differences in the rates of urinary tract infection, BK virus infection, urine leakage, narrowing in the ureter, the cost savings and kidney function between this new procedure and the standard surgical procedure.

Any adverse event will also be investigated. You will be informed about the results from the study. It is hoped that the results of the study will support change in clinical practice and improve recipients’ quality of life. The results will be presented at a medical conference and published in medical journals.

**Part 2 How is the research project being conducted?**

**16 What will happen to information about the participant?**

By signing the consent form you consent to the study. The study doctor and relevant research staff will collect and use personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. The data will be stored in the computer system that requires use of a password in the locked Department office. Your information will only be used for the purpose of this research project and it will only be made known with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to participation in this research project.

It is expected that the results of this research project will be published and or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

Information about your participation in this research project may be recorded in your health records.

In accordance with Western Australia privacy and other relevant laws, you have the right to request access to your information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be made known only with your permission, or as required by law.

**17 Complaints and Compensation**

If you suffer any difficulties as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the complication, free of charge, as a public patient in any Australian public hospital.

**18 Who is organising and funding the research?**

This research project is being conducted by Kidney Transplant Team at Sir Charles Gairdner Hospital. There is no funding available for this study at this stage. There is no commercial sponsorship involved in this study.

**19 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Sir Charles Gairdner Hospital. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**20 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your participation in the study please contact Dr. Bulang He on *6457 3333.* If any urgent medical concerns arise you should present to Emergency Department at Sir Charles Gairdner Hospital for urgent medical attention.

 **Clinical contact person**

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| --- | --- |
| Name | Bulang He |
| Position | Consultant transplant surgeon, SCGH |
| Telephone | 64574055 |
| Email | Bulang.he@health.wa.gov.au |

For matters relating to the study at the site another person you can contact.

**Complaints contact person**

|  |  |
| --- | --- |
| Office | HREC office |
| Telephone | 6457 2999 |
| Email | scgh.hrec@health.wa.gov.au |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | SCGH-HREC |
| Telephone | 64572999 |
| Email | SCGH.hrec@health.wa.gov.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Consent Form**

|  |  |
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| **Coordinating Principal Investigator/****Principal Investigator** | Bulang He |
| **Associate Investigator(s)** | Lingjun Mou, Bryon Jaques, Neil Boudville, Aron Chakera |
| **Location**  | Sir Charles Gairdner Hospital |

**Declaration by Participant**

1. I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
2. I understand the purposes, procedures and risks of the research described in the project.
3. I have had an opportunity to ask questions and I am satisfied with the answers I have received.
4. I believe that my participation in this study is not contrary to my best interests.
5. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the research project without affecting my future health care.
6. I understand that I will be given a signed copy of this document to keep.
7. I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Sir Charles Gairdner Hospitalconcerning my disease and treatment for the purposes of this research project. I understand that such information will remain confidential.

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|  |  |  |  |
|  | Name of Participant (please print) |  |  |
|  | Signature of Participant |  | Date |  |  |
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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  | Name of Study DoctorSenior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

**Form for Withdrawal of Participation**

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| --- | --- |
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| **Location**  | Sir Charles Gairdner Hospital |

**Declaration by Participants**

I wish to withdraw from taking part in the above research project and understand that such withdrawal will not affect my routine treatment, relationship with those treating me or my relationship with Sir Charles Gairdner Hospital.

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|  | Name of Participant (please print)  |   |  |
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|  |  |  |  |
|  | Signature of Participant |  | Date |  |  |
|  |

|  |
| --- |
|  |
|  | Name of Study Doctor/Senior Researcher (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

 Note: All parties signing the consent section must date their own signature