**Participant Information Sheet & Consent Form**

Interventional Study - *Adult providing own consent*

**Lyell McEwin Hospital**

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| **Title** | Prevention of Contrast-Induced Nephropathy by Combined Induced Diuresis with Euvolemic Fluid Resuscitation |
| **Principal Investigators** | Dr Purendra Pati, A/Prof Margaret Arstall |
| **Associate Investigators** | Emily Aldridge, Nitesh Rao, Gus Mugwagwa |
| **Location** | Lyell McEwin Hospital |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you have chronic kidney disease and you are undergoing a coronary angiogram at the Lyell McEwin Hospital. The research project is testing a new prevention method for contrast-induced nephropathy, a disorder that is sometimes caused by coronary angiograms and other procedures involving contrast dye.

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

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

Participation in this research is voluntary. If you do not wish to take part, you do not have to. You will 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. By signing it, you are telling us that you:

* Understand what you have read
* Consent to take part in the research project
* Consent to have the tests and treatments that are described
* Consent to the use of your personal and health information as described.

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

**2 What is the purpose of this research?**

Contrast-induced nephropathy is a relatively common complication for chronic kidney disease patients who are undergoing a procedure involving contrast dye, such as a coronary angiogram. It is characterised by kidney damage that occurs a short time, usually within three days, after having the contrast procedure. We know when a patient experiences contrast-induced nephropathy by observing the levels of creatinine, an enzyme produced by the kidney, in the blood. Creatinine levels are observed from a blood test.

Although contrast-induced nephropathy is relatively rare (affecting only about 15% of chronic kidney disease patients), it can likely be reduced even further through hydration and forced diuresis (increased urine output). Currently, we try to reduce the incidence of contrast-induced nephropathy by hydrating patients with intravenous saline before and after the angiography. However, our research team believe that we may be able to reduce the incidence of contrast-induced nephropathy even further by implementing a new regime of hydration and forced diuresis. This research project aims to identify a new, effective method of reducing rates of contrast-induced nephropathy in patients with advanced stage III, IV and V chronic kidney disease who are having a coronary angiogram at the Lyell McEwin Hospital.

This research project will provide evidence for implementing the new method to prevent contrast-induced nephropathy in these patients. It aims to reduce the rates of contrast-induced nephropathy in our hospital.

This research project involves patients being randomly sorted into one of two groups, the control group (those patients who receive the current usual standard of care, which involves receiving saline through your intravenous drip), and the experimental group (patients who will receive the new, experimental method). Patients in the experimental group will be given a drug to increase their urine output in addition to the saline. This drug is called furosemide. The experimental treatment is called forced diuresis.

Usual care involves receiving saline through an intravenous drip for 12 hours before the angiogram, during the angiogram and for 12 hours after the angiogram. If you are in the experimental group, you will receive saline through an intravenous drip for 1.5-2 hours before your angiogram and receive a dose of furosemide to increase urine output. You will then have your angiogram and have 12 hours of intravenous saline post-procedure.

There is no disadvantage to you being placed in either group.

Medications, drugs and devices have to be approved for use by the Australian Federal Government. Furosemide is approved in Australia to treat fluid retention and high blood pressure.

This research has been initiated by the study doctor, Dr Purendra Pati, and is only being conducted at the Lyell McEwin Hospital.

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

This project will involve you being randomly sorted into either the control or experimental group. The control group will receive the current standard treatment to prevent contrast-induced nephropathy. The experimental group will receive a new, experimental approach to preventing contrast-induced nephropathy.

You will be required to read this Participant Information Sheet and read and sign the Consent Form prior to participating in this study.

Your eligibility to participate will be assessed by your treating doctor. All patients with advanced stage III, IV or V chronic kidney disease undergoing elective or urgent coronary angiography procedures will be approached for the study. If you are allergic to contrast, have a hypersensitivity to furosemide, currently on maintenance dialysis, have had a radiocontrast procedure in the last 72 hours then you will be excluded from the study. You will also be excluded from the study if you experience complications or contraindications from the urinary catheter.

Participation in this research study does not involve any additional tests or procedures while you are in hospital for your angiography. You will be required to attend a short, face-to-face appointment with the study doctor 6 months after you have had your angiogram, which will involve one blood test to check your blood for levels of creatinine.

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is the best for treating a condition. To find out, we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group randomly. You have a 50/50 chance of being put into the experimental group, as patients are being sorted on a 1:1 basis.

You will not be randomised into a group until after you have given written informed consent agreeing to your participation in the study.

This research project has been designed to make sure that the researchers interpret the results in a fair and appropriate way, and avoids the study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as a part of the research project will be provided to you free of charge.

**4 What do I have to do?**

Participation in this research is voluntary. If you do not want to take part, you do not have to. If you choose to not participate in this research study, you will still receive the best possible care.

It is important that you continue to follow your treating doctor’s instructions and treatment plan while you are in hospital for your procedure and during your participation in this research project. This will likely involve you taking your usual medications. If you are unsure about this, please ask your doctor.

For this study, you will only have to undergo one additional blood test at your follow-up appointment, which will occur 6 months after you angiogram.

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

Approximately 160 patients with chronic kidney disease will participate in this project. Half of these patients will be in the control group, and the remaining half will comprise the experimental group. This study is only being conducted at the Lyell McEwin Hospital, in South Australia.

This project involves researchers from the Lyell McEwin Hospital and the University of Adelaide working in collaboration.

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

Participating in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information Sheet and Consent Form to sign and you will be given a copy to keep. A copy will also be kept in your medical records.

Your decision to take part, to not take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Lyell McEwin Hospital.

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; you may choose to simply receive the current standard treatment of saline infusion (which is the same as the treatment provided in the control group). Your study doctor will discuss these options with you before you decide whether to take part, or to not take part, in this research project. You can also discuss the options with your local doctor.

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

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include identifying a method of preventing contrast-induced nephropathy that is more effective that the current treatment.

There will be no clear benefit to you from your participation in this research.

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

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about that may be serious. This is unlikely, however, as furosemide is a commonly used drug which has been researched and tested extensively. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, some side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects.

Possible side effects of furosemide include gastrointestinal upset, itchiness, restlessness and headaches. If you experience any of these side effects, or any other symptoms, please tell your treating physician straight away. Possible rare side effects of the forced diuresis treatment can include low potassium and fluid overload. These side effects can be treated. Adverse side effects caused by furosemide are very rare and can include anaphylaxis and central nervous system damage. If you have any concerns about these possible side effects, please talk to your study doctor and/or treating physician.

Having an intravenous cannula inserted may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

**10 What will happen to my test samples?**

The research project does not require any additional collection or storage of tissue. The study investigators will record your levels of creatinine in your blood for research purposes, but your blood will not be stored. You will be required to provide one extra blood sample at the 6-month follow-up appointment for us to check your creatinine levels.

**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, your 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 arrange 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.

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

**12 Can I have other treatments during this research project?**

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and your treating physician about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. Your study doctor should also explain which treatments or medications need to be stopped for the time you are involved in the research project.

Your study doctor will explain which treatments or medications need to be stopped for the angiogram and possibly for the time you are involved in the research project.

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

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

If you decide to withdraw during the research study, it is likely you will have to continue with the treatment that you have already started. In this instance, your information and outcome will not be recorded as a part of the study.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal 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 to comply with the law. You should be aware that data collected by the sponsor up to the time you withdraw 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?**

Although unlikely, this research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

* Unacceptable side effects
* The treatment is shown to not be effective
* The treatment is shown to work and does not require further testing
* Decisions made by local regulatory/health authorities

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

You will be contacted 6 months after your angiography and participation in this research project to have a face-to-face meeting with the study doctor. You will also be required to give a blood sample to test the creatinine levels in your blood.

The results of the study will not be reported to individual participants.

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

**16 What will happen to information about me?**

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. You will be assigned with a unique study identification number so that your information is not identifiable. The file containing the link between your personal identification information and your study identification number will be kept separate from the research study data to ensure your confidentiality is maintained. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Only the study investigators will have access to your information.

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 your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for verifying the procedures and the data) by the institution relevant to this Participant Information Sheet, the Lyell McEwin Hospital, or as required by law. By signing the consent form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated 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 relevant Australian and South Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research 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 not be disclosed without your permission unless required by law.

**17 Complaints and compensation**

If you suffer any injuries or complications 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 injury or complication, free of charge, as a public patient in any Australian public hospital.

Your participation in this project does not affect any rights you have to compensation under common law.

If you have any concerns about the project, you may contact the study coordinator, Emily Aldridge, on 0423 272 632, or via email at emily.aldridge@adelaide.edu.au. For complaints about the project, please contact the complaints contact person (details on the next page).

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

This research project is being conducted by the Lyell McEwin Hospital and the University of Adelaide. It will take place at the Lyell McEwin Hospital. This study has been initiated by the study doctor, Dr Purendra Pati.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than his or her ordinary wages).

You will not receive any financial benefit for your participation in this study.

The research team have no declarations of interest to make.

**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 the Queen Elizabeth Hospital (TQEH/LMH/MH).

**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 that may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on 0456 317 481 or any of the following people:

**Clinical contact person**

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| --- | --- |
| Name | Dr Purendra Pati |
| Position | Consultant Cardiologist |
| Telephone | 0456 317 481 |
| Email | purendra.pati@sa.gov.au |

**Study Coordinator**

|  |  |
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| Name | Emily Aldridge |
| Position | Study Coordinator |
| Telephone | 8182 9726 / 0423 272 632 |
| Email | emily.aldridge@adelaide.edu.au |

**If you wish to receive a copy of the study results, you may request this in writing from the study coordinator:**

Emily Aldridge

Clinical Trials Unit

Level 2, Lyell McEwin Hospital

Haydown Rd

Elizabeth Vale, SA, 5112

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:

**HREC Executive Officer**

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| Reviewing HREC name | TQEH/LMH/MH HREC |
| HREC Executive Officer | Heather O’Dea |
| Telephone | 8222 6841 |
| Email | health.CALHNResearchEthics@sa.gov.au |

**Consent Form -** *Adult providing own consent*

**Prevention of Contrast-Induced Nephropathy by Combined Forced Diuresis with Euvolemic Fluid Resuscitation**

*Lyell McEwin Hospital*

**Principal Investigators:** Dr Purendra Pati, A/Prof Margaret Arstall

**Associate Investigators:** Emily Aldridge, Nitesh Rao, Gus Mugwagwa

**Declaration by Participant**

* I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
* I understand the purposes, procedures and risks of the research described in the project.
* I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Lyell McEwin Hospital concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.
* I have had an opportunity to ask questions and I am satisfied with the answers I have received.
* I freely agree to participate in this research project as described and understand that I am free to withdraw at any time without affecting my future health care.
* I understand that I will be given a signed copy of this document to keep.

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

|  |
| --- |
|  |
|  | Name of Witness\* to Participant’s Signature (please print) |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older. Only to be completed when the investigator is not present.

**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 Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

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