***SUNSHINE COAST HOSPITAL AND HEALTH SERVICE***

**Participant Information Sheet/Consent Form**

*Person Responsible*

|  |  |
| --- | --- |
| **Title** | Citrate metabolism in critically ill patients receiving continuous renal replacement therapy  using regional citrate anticoagulation |
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|  |  |
| **Short Title** | CiMet |
| **Principal Investigator** | Dr Chris Anstey |
| **Associate Investigator(s)** |  |
| **Location** | SCUH Intensive Care Unit, SCHHS |

**Part 1 What does participation involve?**

**1 Introduction**

The patient is invited to take part in this research project. This is because the patient requires renal dialysis.The research project is designed to measure the breakdown products of the anticoagulant (blood thinner) used for the dialysis machine to run effectively.

This Participant Information Sheet/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 the participant 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 the participant can take part, you might want to talk about it with a relative, friend or the patient’s local doctor.

Participation in this research is voluntary. If you don’t wish the patient to take part, the patient doesn’t have to. They will receive the best possible care whether or not they take part.

If you decide you want the patient 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 the participant taking part in the research project

• Consent to the participant having the tests and treatments that are described

• Consent to the use of the participant’s personal and health information as described.

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

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

Patients often require a renal dialysis (kidney) machine when there is significant kidney failure, or if there are abnormal levels of acids, salts or drugs within the blood. Every patient who needs this treatment must have a tube inserted into a vein in the neck or groin. Blood is removed from the patient by the dialysis machine, a thinning agent is added so the filter does not clot, and the waste products are removed from the blood by pumping it past a filter. Once the blood has been cleaned it is returned to the patient via the same tube in their vein. The residual thinning agent left in the blood is broken down by the liver.

At the moment we use a specific blood thinning agent that is both effective and safe – it is in fact a natural chemical found in everyone’s body called sodium citrate. Sodium citrate fluid is approved in Australia to be used as an anticoagulant for patients on a dialysis machine. In order to investigate the breakdown products of sodium citrate, we propose to collect blood samples regularly and measure the concentrations of these breakdown products.

We have designed the study so that both males and females are eligible to participate as long as they are 18 years of age or older, do not have significant liver disease nor any history of high blood lipids or prescribed treatment for high blood lipids.

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

All patients requiring renal dialysis will be screened for eligibility. Consent to take part will be required. A consent form will be signed prior to any study assessments being performed.

The process of dialysis will be the same as normal however by agreeing to enter the study the participant will have approximately 10 millilitres (2 teaspoons) of extra blood taken every day, whilst on dialysis, so we can measure the concentrations of citrate. This blood is taken from an arterial line which will already be in place for patients in ICU on renal dialysis. The procedure of taking blood from these lines is painless. Routine blood tests will also be taken to measure levels of acids and salts in the blood – this is normal practice when patients are on the dialysis machine.

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

There are no additional costs associated with participating in this research project, nor will you or the participant be paid.

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

This is a single-site study only conducted in this Intensive Care Unit. There will be 20 participants taking part in this project. We will collaborate with members of the Pathology service based at the Royal Brisbane and Women’s Hospital (RBWH) who will assist with testing the blood.

**5 Does the participant have to take part in this research project?**

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

If you do decide that the participant can take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether the participant can take part or not take part, or take part and then be withdrawn, will not affect the participant’s routine treatment, your or the participant’s relationship with those treating them, or the participant’s relationship with the Intensive Care Unit or the Sunshine Coast Hospital and Health Service

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

The participant does not have to take part in this research project to receive treatment at this hospital. They will receive renal dialysis as part of their care if it is required whether they participate or not.

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

There is no anticipated benefit to the participant from enrolling in this research. However by measuring the concentration of the breakdown products of citrate in blood we will gain vital information to make it easier in the future to balance acids and salts within the blood of patients who are on the dialysis machine.

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

We don’t anticipate there being any more risk than the standard risks of being on the dialysis machine. All other treatments and care on the ICU will be the same.

**9 What will happen to the participant’s test samples?**

Samples of the participant’s blood from the dialysis machine obtained for the purpose of this research project to specifically test for the breakdown products of citrate will be prepared onsite for transportation to the to RBWH for testing to take place. Blood will not be stored or kept after testing so all samples will be destroyed as per RBWH standard procedures. Part of the sample will be tested locally for the concentration of citrate.

Blood samples taken as part of routine care for a patient on dialysis will be processed onsite as per all standard ICU blood tests.

Blood tests results for research purposes will be de-identified in the data collection. Participant’s name and identifying details are replaced with a numerical code (study number) and this code (number) is assigned to their test results to maintain privacy.

**10 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 participant’s study doctor will tell you about it and discuss with you whether you want the participant to continue in the research project. If you decide to withdraw the participant, their study doctor will make arrangements for their regular health care to continue. If you decide that the participant can continue in the research project you will be asked to sign an updated consent form.

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

It should be noted that samples will be batch tested up to 14 days after collection therefore study results will not be available for clinical use. All routine results will be available as per usual practice.

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

Participation in this study does not prevent the participant from receiving any other appropriate treatments they may require.

**12 What if I withdraw the participant from this research project?**

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

If you do withdraw the participant during the research project, the study doctor and relevant study staff will not collect additional personal information from the participant, 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 law. You should be aware that data collected by the research team up to the time you withdraw the participant 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.

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

We do not envisage this research project stopping unexpectedly however any project can be stopped for a number of unforeseeable reasons.

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

There is no requirement for any specific follow-up relating to this research project. Once all the data has been collected and analysed it may be published in a medical journal or presented at medical conferences/forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified

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

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

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about the participant for the research project. By signing the consent form you agree to the study team accessing health records if they are relevant to participation in this research project. Information about participation in this research project may be recorded in the participant’s health records.

Any information obtained in connection with this research project that can identify the participant will remain confidential and securely stored. The data from the blood test results will be collected and analysed. The data will be coded so that only the researchers will be able to re-identify from where the blood results came from. All data will be held securely on the hospital server (computer) for a period of up to 15 years so that further analysis may be performed on the data in the future if needed. The participant’s 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.

The participant’s health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities, the institution relevant to this Participant Information Sheet, Research Governance at SCHHS 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.

**16 Complaints and Compensation**

If you have any concerns or complaints you should contact the study team or complaints contact person listed below. Participants may seek legal advice and compensation may be available under compensation guidelines.

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

This research project is being conducted by Dr Chris Anstey and funded through Intensive Care Research Department funds and research grants. The participant will not benefit financially from their involvement in this research project. No member of the research team will receive a personal financial benefit from the participant’s involvement in this research project (other than their ordinary wages).

**18 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 Prince Charles 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.

**19 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 the participant has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the principal study doctor, Chris Anstey on (07) 5202 1546 or any of the following people:

**Clinical contact person**

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| --- | --- |
| Name | *ICU Research Coordinators* |
| Position | *Research Coordination* |
| Telephone | *(07) 52025222 (ICU direct 24 hours)* |
| Email | [*Lauren.Murray@health.qld.gov.au*](mailto:Lauren.Murray@health.qld.gov.au) |

For matters relating to research at the site at which the participant is participating, the details of the local site complaints person are:

**Complaints contact person**

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| --- | --- |
| Name | *Megan Rutter* |
| Position | *Research Governance Officer* |
| Telephone | *(07) 52022991* |
| Email | *SC-Research-governance@health.qld.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:

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| --- | --- |
| Reviewing HREC name | *The Prince Charles Hospital HREC* |
| HREC Executive Officer | *Executive Officer* |
| Telephone | *(07) 31394198* |
| Email | *ResearchEthics@health.qld.gov.au* |

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

**Consent Form – Person Responsible**

|  |  |
| --- | --- |
| **Title** | Citrate metabolism in critically ill patients receiving continuous renal replacement therapy  using regional citrate anticoagulation |
|  |  |
| **Short Title** | CiMet |
| **Principal Investigator** | Dr Chris Anstey |
| **Associate Investigator(s)** |  |
| **Location** | SCUH Intensive Care Unit, SCHHS |

**Declaration by Person Responsible**

I am the Person Responsible for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (the 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 have had an opportunity to ask questions and I am satisfied with the answers I have received.

I believe that the participation of the participant in this study is not contrary to their best interests.

I freely agree to the participant participating in this research project as described and understand that I am free to withdraw the participant at any time during the research project without affecting their future health care.

I am aware of my responsibilities as the Person Responsible for the participant and I understand that I will be assisting the participant in meeting their responsibilities whilst they are participating in this study.

I understand that I will be given a signed copy of this document to keep on behalf of the participant.

I give permission for the participant’s doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Sunshine Coast Hospital & Health Serviceconcerning the participant’s 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) |  | | | | | | |  | |
|  |  |  | | | | | | |  | |
|  | Name of Person Responsible (please print) | | |  | | | | |  | |
|  |  | | |  | | | | |  | |
|  | Relationship of Person Responsible to Participant | | | | |  | | |  | |
|  |  | | | |  | | | |  | |
|  | Signature of Person Responsible | |  | | | | 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 person responsible 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.

**Form for Withdrawal of Participation – Person Responsible**

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| --- | --- |
| **Title** | Citrate metabolism in critically ill patients receiving continuous renal replacement therapy  using regional citrate anticoagulation |
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| **Short Title** | CiMet |
| **Principal Investigator** | Dr Chris Anstey |
| **Associate Investigator(s)** |  |
| **Location** | SCUH Intensive Care Unit, SCHHS |

**Declaration by Person Responsible**

I wish to withdraw the participant from taking part in the above research project and understand that such withdrawal will not affect the participant’s routine treatment, relationship with those treating them or their relationship with the Sunshine Coast Hospital and Health Service.

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|  |  |  | | | | | | |  |
|  | Name of Participant (please print) |  | | | | | | |  |
|  |  |  | | | | | | |  |
|  | Name of Person Responsible (please print) | | |  | | | | |  |
|  |  | | |  | | | | |  |
|  | Relationship of Person Responsible to Participant | | | | |  | | |  |
|  |  | | | |  | | | |  |
|  | Signature of Person Responsible | |  | | | | Date |  |  |
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|  | Name of Study Doctor/  Senior Researcher (please print) | |  | | |  | |
|  | | | | | |  | |
|  | Signature |  | | Date |  | |  |
|  | | | | | | | |

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