****Renal Services**

**Participant Information Sheet**

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| Study title: | **A pharmacokinetic (pK) study comparing the clearance of Vancomycin during haemodialysis using Medium cut-off membrane (Theranova) and High-Flux membranes (Revaclear)**  |
| Locality: | **Hastings Hospital, Hawke’s Bay, New Zealand**  | Ethics committee ref.:  |  |
| Lead investigator: | **Dr. Hussain Allawati** | Contact phone number: | **06 878 8109 /** **021 055 9711** |

*Please let us know if you need an interpreter.*

*You are invited to take part in a study on comparing the clearance of antibiotic called vancomycin using two different types of dialysers.*

*Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.*

*This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.*

*If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.*

*This document is [ 7 ] pages long, including the Consent Form. Please make sure you have read and understood all the pages.*

What is the purpose of the study?

*The purpose of this study is to compare how the antibiotic ‘vancomycin’ is cleared on haemodialysis using two different types of dialyzers.*

*Up to recently you were dialysed on a high-flux dialyser and we recently switched to a newer type of dialyzer called Theranova. The antibiotic is washed out on these types of Theranova dialyzers. We know how this happens on the old (Revaclear) dialyzer and now want to see how the antibiotic is washed out from your body with this new type of dialyzer (Theranova).*

*You will only be given the antibiotic if you need it for medical reasons such as treating an infection.*

*By understanding how the antibiotic is washed out of your body using the new dialyser, this will help us decide how much antibiotic you will need and how often you will need it. This will help us in the future to treat other dialysis patients who might need this antibiotic and are using this dialyser.*

*This antibiotic is given routinely to anyone on dialysis who needs it to treat certain conditions such as infections.*

*This is an open label study meaning that you will be aware and informed that you are being given this antibiotic as part of your care.*

*There is no financial funding associated with this study.*

*The investigator (Hussain Allawati) is affiliated to Hastings Hospital at Hawkes Bay District Health Board. The contact numbers are 06 878 8109 / 021 055 9711 should you have any questions or concerns about the study.*

*The study is approved by the Ethics committee*

What will my participation in the study involve?

*You have been chosen to be participate in this study because your dialysis doctor has decided to give you this antibiotic (vancomycin) to treat your condition which is the standard thing to do. You are currently getting dialysis using the Theranova dialyzer.*

*During the study, you will be given the antibiotic over six Dialysis days (total of two weeks) which is the duration of the study. We will be alternating each session between the Theranova dialyzer and the high-flux dialyzer. During the session, we will take a total of 7 samples of your blood for measuring the antibiotic level.*

*Once you are connected to the dialysis machine, we will get a blood sample to check the antibiotic level before you start dialysis. Once dialysis has started, we will get some more blood samples at specific times to check the antibiotic level. You will then be given your required vancomycin dose during dialysis (usually in last 1-2 hours). Once you have finished dialysis and antibiotics, you will be kept here for another 30 minutes to make sure that you are well and your nurse will take another blood sample. You then will be able to go home if there are no issues.*

*Participating in this study will not affect or increase the number of dialysis sessions or hours. You will still have to come at your usual dialysis appointment times.*

*During the study we will collect your information about your date of birth, gender, ethnic origin, Medical history, medications and a physical exam on day one of the study. We will get information about your dialysis access (fistula or a tunneled line), blood flow though the machine and some other information about the machine itself. During each session we will check your vital signs (temperature, oxygen saturation, respiratory rate, blood pressure and heart rate), dry weight (kg) and weight on day of study.*

*If you have concerns about the antibiotics or have side effects, then you should let us know immediately. Should you participate, your GP will receive notification of your involvement in the study.*

*If you do not wish to participate, you will still receive the antibiotic that your doctor has prescribed over the two-week period. The only difference is that we will not be doing blood test during dialysis or after dialysis or change your dialyzer. You will still receive the usual standard care, i.e. your care will not be affected.*

What are the possible benefits and risks of this study?

*If you participate in this study the potential side effects may be related to the antibiotics. The most serious one is anaphylaxis (serious allergic reaction) which is rare. You would have already received your first dose prior to being enrolled in this study. If this was to happen, then we will stop the antibiotic immediately and treat you with medications for it.*

*Sometimes a condition called Red Man syndrome can occur with this antibiotic if it is given too quickly. You may develop redness on your face and skin and itch. It is not a life-threatening condition and can be treated with giving some anti-histamines and/or steroids and increasing the duration over which we give you the antibiotic.*

*Being involved in this study should not affect your family or whānau.*

*By being involved in the study, it will help us understand how the antibiotic is washed out of your body using the new dialyser, it will help us decide how much antibiotic you will need and how often you will need it. This will help us in the future to treat other dialysis patients who might need this antibiotic and are using this dialyser.*

*During the study period, the investigator will make sure that you are getting the right dose of antibiotics and that you are getting better from you condition that required you to have the antibiotic. If the antibiotic does not make you feel better, then this will be reviewed, the antibiotic may be changed and appropriate care will be provided. If you were to develop a reaction that is probably related to the drug and makes you unwell, then you will be withdrawn from the study and we will ensure that you are followed up to assess that they you are well and other form of antibiotics are provided if needed.*

Who pays for the study?

*If you agree to be part of the study, this will be free for you.*

What if something goes wrong?

*If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC which we will help you do. If your claim is accepted, you will receive funding to assist in your recovery.*

*If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.*

What are my rights?

*This participation is absolutely voluntary. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time without having to explain why and it will not affect the care you receive.*

*You have the right to access the information we have collected about you in the study at any time. You will be immediately told about any adverse events or side effects we or you notice during the study. If we find anything during the study that you already do not know, then this will be made available to you by the investigator.*

*All information provided to the investigator and/or the staff helping the investigator will be kept strictly confidential and confined to the clinical personnel involved in conducting the study as part of the permanent record. All data and medical information gathered for each subject will be identified only by a unique subject study number.*

What happens after the study or if I change my mind?

*Once the study is completed, you will be switched permanently to your original dialyzer (Theranova). The antibiotic may be given/continued to you after the study is completed as deemed necessary by your dialysis doctor.*

*All information provided to the investigator and/or the staff helping the investigator will be kept strictly confidential and confined to the clinical staff involved in conducting the study as part of the permanent record. The information gathered could be used for future presentations or publications. You will not be able to be identified in the presentation or publication.*

*Individual information obtained during this study is confidential and will not be disclosed except when the data are needed by your personal physician or other medical personnel responsible for your care. Otherwise your identity will not be known in any publication.*

*At conclusion of the study, the blood samples obtained will be discarded at the local laboratory.*

*Once you have completed the study, you will receive written notification about it. The study findings will be made available within six months of completing the study.*

Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

 *Investigator: Dr. Hussain Allawati*

 *Position: Nephrology Registrar*

 *Locations: Renal unit, Hastings Hospital, Hawkes bay DHB*

 *Telephone number: 06 878 8109 / 021 055 9711*

 *Email:* *hussain.allawati@hbdhb.govt.nz*

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

For Maori Heath support, please contact :

*Name: Laura Gemmell*

*Maori Health unit*

 *Telephone number: 06 878 8109 ext 5779*

 *Email: admin.maorihealth@hbdhb.govt.nz*

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

 Phone: 0800 4 ETHICS

 Email: hdecs@moh.govt.nz

**Renal Services**

**Consent Form**

**If you need an INTERPRETER, please tell us.**

*If you are unable to provide interpreters for the study, please clearly state this in the Participant Information Sheet*

I have been asked if I need an interpreter. Yes 🞏 No 🞏

**Please tick to indicate you consent to the following**

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| --- | --- | --- |
| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.  | Yes 🞏 | No 🞏 |
| I have been given sufficient time to consider whether or not to participate in this study. | Yes 🞏 | No 🞏 |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. | Yes 🞏 | No 🞏 |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. | Yes 🞏 | No 🞏 |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. | Yes 🞏 | No 🞏 |
| I consent to the research staff collecting and processing my information, including information about my health. | Yes 🞏 | No 🞏 |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. | Yes 🞏 | No 🞏 |
| I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study. | Yes 🞏 | No 🞏 |
| I agree to my (blood) samples being sent to the local laboratory for analysis and I am aware that these samples will be disposed of using established guidelines for discarding biohazard waste. | Yes 🞏 | No 🞏 |
| I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study. | Yes 🞏 | No 🞏 |
| I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. | Yes 🞏 | No 🞏 |
| I understand the compensation provisions in case of injury during the study. | Yes 🞏 | No 🞏 |
| I know who to contact if I have any questions about the study in general. | Yes 🞏 | No 🞏 |
| I understand my responsibilities as a study participant. | Yes 🞏 | No 🞏 |
| I wish to receive a summary of the results from the study. | Yes 🞏 | No 🞏 |

**Declaration by participant:**

I hereby consent to take part in this study.

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| Participant’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

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| Researcher’s name: |
| Signature: | Date: |