**THE TOWNSVILLE HOSPITAL**

**STUDY INFORMATION & INFORMED CONSENT**

This informed Consent form is for male and female patients who undergo renal haemodialysis at The Townsville Hospital and The North Ward Dialysis Units. The participants are invited to be involved in examining the effect of dialysate sodium concentration on interdialytic weight gain. The title of our research project is “The effect of low dialysate sodium on interdialytic weight gain and hypertension in patients undergoing chronic intermittent haemodialysis – a prospective study in The Townsville Hospital and The North Ward Dialysis Units”

**Name of Principal Investigator:** Dr. Catherine Wilkinson

**Names of Co-Investigators:** Dr. Waqas Baig

Dr. Nasir A. Shah

 Dr. George Kan

 Dr. Vali Manickam

 Dr. Vikas Srivastava

Vicki Hartig

Amy Borrows

Kim Hughes

Anne Forrest

**Name of Organization:** The Townsville Hospital

**This project has been reviewed and approved by the Townsville Hospital and Health Service Human Research Ethics Committee. For concerns relating the conduct of this project contact:**

HREC Chairperson

            Phone: 07 4433 1440

            Email: TSV-Ethics-Committee@health.qld.gov.au

**This Informed Consent Form has two parts:**

* Information Sheet (to share information about the research with you)
* Certificate of Consent (for signatures if you agree to take part)

**PART I: Information Sheet**

**Introduction**

This study will be conducted at The Townsville Hospital and The North Ward Dialysis Units. We are doing research on patients with end stage renal disease who require haemodialysis. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. If you have questions later you can ask me, the study doctor, or the staff.

**Purpose of the research**

Significant weight gain and poorly controlled blood pressure are commonly seen in patients with end stage renal disease on intermittent hemodialysis. There is evidence that these complications are due to not enough salt being removed from the body during hemodialysis. The hemodialysis machine currently uses a standard strength of sodium during each hemodialysis session. We think that if we reduce this concentration, we may be able to help better control your blood pressure, and decrease the amount of weight you gain between dialysis sessions. The reason we are doing this research is to find out if the low sodium fluid is better than the regular concentration that is currently being used.

**Type of Research Intervention**

This research will involve an alteration to the settings on the hemodialysis machine. For you, each dialysis session will remain much the same.

**Participant selection**

We are inviting all adults with end-stage renal disease on haemodialysis who attend the renal unit at The Townsville to participate in the research looking at the effect of different concentrations of the sodium dialysate.

**Voluntary Participation**

Your participation in this research is entirely voluntary - it is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered at The Townsville Hospital and The North Ward Dialysis Units for people requiring hemodialysis. You can change your mind later and stop participating even if you agreed earlier.

**Procedures and Protocol**

You will continue to have your hemodialysis sessions as you would normally. We will make some changes to the setting on the hemodialysis machine when you come in. Instead of using a 140mEq/L sodium dialysate, we drop the sodium concentration to 138mEq/L, and then 136mEq/L, over a 2-week period. The hemodialysis itself is routine, but the use of this new sodium dialysate is a part of our research.

We may need to take blood from you at varying points during the study, which is routinely done during dialysis sessions. At the end of the research, in 1 year, any left over blood sample will be destroyed.

**B. Description of the Process**

During the research you will continue to attend your usual hemodialysis sessions. At each session we will do the following:

* Measure your weight, and blood pressure
* Take a sample of blood a week after changing dialysate sodium (we will time it in such a way that it concides with the routine blood tests to avoid extra test)
* Monitor your vital signs while you are on the hemodialysis machine

Although there will not be any additional clinic appointments, we will follow-up with you regularly when you are on dialysis:

* We will ask you a few questions about your health and how you have been finding the dialysis sessions with the sodium fluid
* This information will be documented, and saved in your electronic medical records
* We will look through your results and see how you have been tolerating the new regimen

**Duration**

The research takes place over 8 weeks in total. During that time, you will attend your regular dialysis sessions as usual. There will not be any additional clinic appointments, as all of the follow-up will be done while you are at your normal dialysis sessions. At the end of 8 weeks, the research will be finished, and you will return to using your usual sodium dialysate concentration.

**Risks & Side Effects**

As you will continue on your usual hemodialysis schedule, all the risks involved with hemodialysis itself will still stand. By participating in this research it is possible that you will be at greater risk than you would otherwise be. As already mentioned, there can be some unwanted effects when using a different sodium dialysate. These include:

Minor Side Effects:

* Nausea, vomiting, cramps, headache
* Low blood pressure
* Chest pain

Major Side Effects:

* Dialysis disequilibrium syndrome (DDS): This side effect is extremely rare. It can present as a seizure in its worse form. It is very unlikely in patients who have been on dialysis for some time. To decrease the risk of this happening, we will slowly drop the dialysate sodium concentration slowly over 2 weeks. If this very unlikely side effect occurs, we will treat it with additional short haemodialysis sessions with normal dialysate sodium to bring the blood sodium levels back up.

We will follow you closely and keep track of any unwanted effects or problems. If unwanted side effects arise, we may use other medicines to treat the reactions. If your symptoms are very severe, we may stop the use of the experimental sodium dialysate. If this is necessary we will discuss it with you, and you will always be consulted before we change your treatment.

**Benefits**

As you know, it is very important to maintain your weight as close to your dry weight as possible. This is normally quite difficult, and we try to achieve this by restricting your fluid intake, and putting you on certain medications that help us to remove excess fluid. It is possible that the new protocol will make you feel less thirsty, making it easier to stick to your fluid restriction. This, in turn may also help control your blood pressure better.

That being said, your symptoms may not improve, and you may find that there has been no benefit for you. Your participation is still very important, and appreciated. It will help us find the answer to our research question. There may not be any benefit to the society at this stage of the research, but future generations may benefit depending on the outcome.

**Confidentiality**

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will ensure that this information will be kept safe, and secure.

**Sharing the Results**

The knowledge that we get from doing this research will be shared with you at reviews in the dialysis unit and clinic appointments before it is made widely available to the public. Confidential information will not be shared. After the results of the study are finalized, we will publish the results so that other interested people may learn from our research.

**Right to Refuse or Withdraw**

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.

**Alternatives to Participating**

If you do not wish to take part in the research, you will be provided with the established standard treatment available at The Townsville Hospital and The North Ward Dialysis Units. We normally use a 140mEq/L concentration of sodium dialysate.

**Who to Contact**

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

**Principal Investigator:** Dr. Catherine Wilkinson

4433 1111/Catherine.Wilkinson@health.qld.gov.au

**Renal ILO:** Jo Alderman 4433 1111/jo.alderman@health.qld.gov.au

**PART II: Certificate of Consent:**

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| --- | --- |
| **Short Title** | *The effect of lowering dialysate sodium concentration on hypertension and weight gain in patients on maintenance haemodialysis* |
| **Protocol Number** | *V1.2 – 10/09/2016* |
| **Principal Investigator** | *Dr. Catherine Wilkinson* |
| **Location** | *Townsville Hospital Health Services* |

**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 have had an opportunity to ask questions and I am satisfied with the answers I have received.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Townsville Hospital Health Servicesconcerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

I consent to the storage and use of blood samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

• This specific research project

• Other research that is closely related to this research project

• Any future research

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 |  |  |
|  |

**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 |  |  |
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† 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.