**Informed Consent Form (ICF)**

*This Informed Consent Form is for men and women agree to participate in the clinical trial titled: Renal Outcome with Empagliflozin in non-diabetic Chronic Kidney Disease Patients: A Randomized Control Trial*

**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)**

**You will be given a copy of the full Informed Consent Form**

**PART I: Information Sheet**

**Introduction**

We are the research team, working on RECONNECT clinical trial. We are doing research on non-diabetic Chronic Kidney Disease Patients, which is common in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask us to stop as we go through the information, and we will take time to explain. If you have questions later, you can ask them of any of us, the study doctor, or the staff.

**Purpose of the research**

The objective of this clinical trial is to demonstrate that Empagliflozin 10mg added with standard care for chronic kidney disease patients will slow down the progression of the disease. Chronic kidney disease is a serious public health problem as it is one of the major causes of hospitalization worldwide. Despite receiving medical treatment, the outcomes remain either fast progression to dialysis or transplantation. Empagliflozin is added in KDIGO guidelines for treatment of diabetic chronic kidney disease patients. There is evidence that it could help patients with non-diabetic chronic kidney disease but no conclusive studies have been done on this.

**Type of Research Intervention**

This research will involve the patients taking 10mg orally (tablet) of empagliflozin daily.

**Participant selection**

We are inviting all adults with the following criteria to participate in the study. Circle the answer that best describes your situation.

|  |  |  |
| --- | --- | --- |
| Have you ever been diagnosed with chronic kidney disease stage 3 and 4? | Yes | No |
| Have you ever been diagnosed with diabetes? | Yes | No |
| Are you 18 years old or older? | Yes | No |
| Have you had any major surgery during the last 6 months? | Yes | No |
| For ladies, are you pregnant or nursing? | Yes | No |
| Are you on any transplantation list? | Yes | No |
| Are you on dialysis? | Yes | No |
| Are you allergic to any drug? | Yes | No |
| Do you have any malignancy? | Yes | No |

**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. You may change your mind later and stop participating even if you agreed earlier.

**Information on the Trial Drug Empagliflozin:**

Empagliflozin is an orally available inhibitor of the renal dependent glucose co-transporter 2(SGLT-2) which is mainly used for reduction of blood glucose in patients with type 2 diabetes mellitus. It leads to increased urinary sodium and glucose excretion. The effect of sodium excretion becomes nil within a few days but the effect on urinary glucose continues.

The safety profile of this drug is well established and has no major risk factor. Further the bioequivalence of this drug has been studied locally as well.

**Procedures and Protocol**

At the beginning of the study, you will be randomly assigned to one of two groups: control and treatment. We will collect health information about you, including but not limited to name, birth date, address, phone number, weight, height, and blood pressure. We will also collect blood and urine samples four times: During the first visit, and during three more follow-up visits that are 30 days apart. The control group will continue to receive standard therapy whereas the treatment group will involve taking 10mg orally (tablet) of empagliflozin daily. In total, we will take four blood samples and four urine samples.

**Duration**

The research takes place over 120 days or 4 months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility five times, for 30 minutes each day. We would like to meet with you one month after your last clinic visit for a final check-up.

In total, you will be asked to come 5 times to the clinic in 4 months. At the end of four months, the research will be finished.

**Side Effects:**

The approved dose of empagliflozin is 25mg. We will be using 10mg dose in our study.

There are no major side effects of the drug. Some of the reported side effects are:

Increased urgency in urination, change in the color of vaginal discharge and side pain.

**Risks**

There is no extra risk for participating in this study but in case you report any side effect, the on panel doctors will examine and provide you with the necessary care following on the facilities guidelines.

**Benefits**

The results of this study will be used for the improvement in the treatment protocol of the patients in this population. This will provide the participants with the opportunity to be engaged in their care and treatment management.

**Confidentiality**

With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

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 lock that information up with a lock and key.

**Sharing the Results**

The knowledge that we get from doing this research will be shared with you through publications, and conferences. Confidential information will not be shared. Moreover, we will publish the results in order that other interested people may learn from our research. You will be provided with the results from the study.

**Right to Refuse or Withdraw**

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

**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 hospital.

**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: Dr Zara Nisar, nisarzara@gmail.com, 0323-9519743, if any information regarding the treatment is to be asked contact Consultant Nephrologist Dr Hassan Sajjad, 0333-5031589.

**PART II: Certificate of Consent**

**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.**

**Print Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **Day/month/year**

**If illiterate**

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

**I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**

**Print name of witness\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ AND Thumb print of participant**

**Signature of witness \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **Day/month/year**

**Statement by the researcher/person taking consent**

**I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands what will be done:**

**I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

 **A copy of this ICF has been provided to the participant.**

**Print Name of Researcher****/person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Researcher /person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **Day/month/year**