IRB Approved at the
Study Level
Jan 30, 2020

Four Rivers
clinical research

Dear Patient:

Our center is taking part in a new study for patients with type II diabetes and chronic kidney disease. When patients have type II diabetes it can cause many different health problems, such as chronic kidney disease. There is a great need for development of new medications for the treatment of kidney disease.

The purpose of this study is to see if an investigational drug called SEL can potentially slow or delay time to kidney failure in patients with diabetic kidney disease.

If you agree to take part in this study, you will be one of approximately 3300 subjects in this study worldwide.

You may be able to take part in this study if you:

- are 30-80 years old
- have type II diabetes
- have diabetic kidney disease
- are not currently on dialysis

*Note: additional qualification criteria exist

A screening visit would be done first to ensure that you meet all of the necessary safety criteria. All patients who pass the screening criteria will take the study medication (pill) for a period of 5 weeks. After this initial 5 weeks, patients will be randomly selected to either stay on the active treatment or move into the control (placebo) group for the rest of the study duration (estimated 3-5 years). The treatment groups are "double-blinded" meaning that, once in this phase of the study, all participants will take a pill once daily but neither you nor the research staff will know which group you are in.

We make every effort to provide flexible scheduling for our participants and you will also be paid up to $50 at each visit to help offset your time and travel expenses.

If you do decide to take part in this study, all study medication and tests will be provided at no cost. It's also important to note that taking part in a study will not impact the standard visits you have with your own healthcare providers and you will not be asked to stop any of the medications you are currently taking. Our team will regularly update your doctor on your study status and we will also share copies of any labs or exams that are completed during the trial.

Please feel free to contact me if you have any questions, or if you would like to schedule a brief informational visit at our office to learn more.

Thank you,
Dr. David Stricklin, Principal Investigator &
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