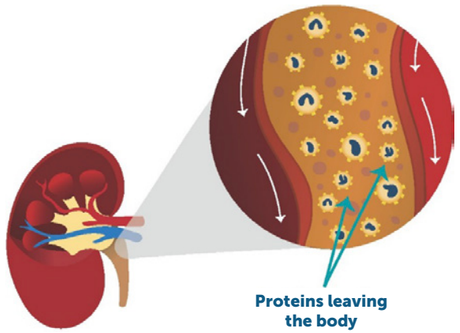
About FSGS

A focal segmental glomerulosclerosis (FSGS) diagnosis means that there is scarring in the cells of the kidney that filter blood. These cells, called glomeruli, work like a coffee filter: they keep necessary protein in the blood while allowing urine to filter out. When glomeruli become scarred (sclerosis), they begin to lose their function, and proteins start leaking into the urine (proteinuria). Continued scarring may lead to kidney failure and the need for dialysis or kidney transplant.

The goal in treating FSGS is to stop or lower the amount of protein lost in the urine as much as possible so that future scarring is minimized, and kidney function is preserved.

FSGS is a serious kidney disease that can only be diagnosed by a kidney biopsy. Treatment is important. After diagnosis and when discussing your treatment plan with your doctor, you may want to ask about this clinical research study designed to treat people with FSGS.



When damaged, the kidney's glomeruli cease to properly filter the blood and allow important proteins to leave the body through urine.

What is a clinical research study?

Doctors and researchers use a clinical research study to learn more about an investigational drug, which is a drug that has not been approved by regulatory health agencies, like the FDA (US Food and Drug Administration). In order to conduct a clinical research study, doctors need people like you to volunteer for participation.

During a clinical research study, participants are carefully monitored and evaluated by a team of healthcare professionals. Even if you choose to participate in a clinical research study, you have the right to stop your participation at any time and for any reason.

Prior to joining a clinical research study, the study doctor and coordinator will review the benefits and risks of study participation with you, as well as answer any of your questions.

To learn more about this study, please contact:

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Considering your next steps when living with

FSGS?

Learn more about this clinical research study of an investigational drug for people who have been diagnosed with focal segmental glomerulosclerosis (FSGS).

This Phase 2a study will test the safety and effectiveness of an oral investigational drug for adults with FSGS. This study will help determine if the investigational drug can reduce proteinuria (increased levels of protein in the urine) while maintaining stable kidney function in adults with FSGS.

Throughout the course of the study, researchers will measure how different doses of the investigational drug impact proteinuria and carefully evaluate kidney-related and other effects of the drug.

The study is sponsored by Boehringer Ingelheim Pharmaceuticals, Inc.

About the investigational drug

The investigational drug is an oral capsule that is taken once a day in the morning, with or without food. While it has been studied in clinical research studies before, it is not approved to treat FSGS. Only FSGS patients who are in clinical research studies like this one can receive it.

The investigational drug will be compared to placebo, which looks like the investigational drug but contains no active medication. Placebo is used to help doctors measure safety and effectiveness of the investigational drug.

Can I participate in this study?

Consider talking with your doctor about whether you are eligible to participate in this study. This study is open to individuals who:

- Are 18 to 75 years of age
- Have been diagnosed with FSGS

Additional criteria will determine if you are able to participate.

What will happen in this study?

Eligible study participants will be randomly assigned (by chance) to 1 of 4 study groups. Three groups will receive the investigational drug and one group will receive placebo. There is a 75% chance of receiving the investigational drug and a 25% chance of receiving placebo. Participants and the study doctor/staff will not know who is in which group, but this information can be provided in the event of an emergency.

All study participants will take their study drug (investigational or placebo) once a day for 12 weeks. Total participation in this study will last approximately 20 weeks, which includes about 7 study visits for health exams and tests and 4 phone calls from the study doctor/staff.

Additionally, during this study, participants may be able to continue taking their current medications for their kidney disease. Participants will also be asked to collect their urine over a 24-hour period at various times throughout the study. They will be provided with containers and instructions on how to collect, store, and bring their samples to the study center.

Does is cost anything to join this study?

There is no cost to participate in the study. All tests and procedures associated with the study are provided at no cost to you. You may receive compensation for your time and effort.

Who will manage my care during this study?

During the consent process, you will meet with a study coordinator who, in addition to your doctor, will serve as a point of contact throughout the course of the study. The study coordinator will be available to answer questions and/or will send reminders to ensure that you stay on track for appointment scheduling.