

Why are you invited?

You are being asked to take part in this clinical study because you have chronic kidney disease and you don't have diabetes.

Purpose of the study

Patients with chronic kidney disease have declining kidney function.

The main purpose of this study is:

- to learn if the study drug helps delay chronic kidney disease progression in patients without diabetes,
- to learn if the study drug is safe,
- to learn how it affects the body.



Expected benefits and goals

- The study will help doctors learn more about this investigational drug and understand if it works in patients with chronic kidney disease. This information may help future patients suffering from CKD who don't have diabetes.
- You may benefit from the additional medical evaluations. Many of these tests are done in addition to the local medical standard. This may help to improve future individual therapy and to identify unknown medical risks.

Your rights and making a decision

- Joining the study is entirely up to you.
- Take time to carefully read the information about the study. Ask the study doctor if something is not clear or if you would like to receive more information.
- If you decide not to take part in this study, you will still get your standard medical care.
- You can stop the study drug anytime. Your study doctor will continue to follow up with you to collect important information about your health.
- You can also stop full study participation at any time. In this case, your study doctor may need to contact you in the future for important information. The study doctor will take time to give you a detailed explanation of every aspect of the study, the disease, and the effects of the study drug. Feel free to contact the study doctors if you have any questions or need more information.

Study doctor

Contact information

This study is sponsored by Bayer AG, Germany



FIND-CKD

FIND-CKD Study

Your doctor would like you to consider taking part in the FIND-CKD clinical study.

FIND-CKD is a phase 3 study that will evaluate the use of the study drug finerenone in patients with chronic kidney disease and without diabetes.

Take your time to read this leaflet and the other material that the doctors will provide with information on this study.



What is a phase 3 study?

Phase 3 studies are designed to evaluate a drug's effectiveness in large groups of people with the disease or condition being studied and to monitor the common short-term adverse effects and risks associated with the drug.

The same drug was tested in other studies.



The FIND-CKD study has been reviewed and approved by regulatory health authorities in your country.

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Which drug is being evaluated?

- **Investigational** means that this drug has not been approved for this disease by regulatory and health authorities. It is only available to people who are taking part in this study.
- A **placebo** is used to help learn if the study drug works. The study drug is compared to the placebo, which looks like the study drug but has no active investigational drug in it.
- **Randomization:** a computer program will randomly choose whether you receive the investigational drug or placebo. This helps ensure that the drugs are chosen fairly and comparing the results is as accurate as possible. You will have a 1 in 2 chance of getting the study drug and a 1 in 2 chance of getting the placebo.

Important information about pregnancy

Women of child-bearing potential can take part in this study only if a pregnancy test is negative at Screening Visit and if they use contraception as advised by the study doctor, and as stated in the Informed consent. Women who are pregnant or breastfeeding cannot participate.

Female partners of male participants are not required to use contraception.

Taking part in the study

Screening

2 WEEKS



Treatment

3 TO 4 YEARS



Follow-up

4 WEEKS



You will visit your hospital or clinic about 18 times, and you are expected to take part in the study for about 4 years. Depending on your hospital / clinic, some visits may be performed at home.

The most common side effects

As with any drug, side effects may take place with the Investigational drug. There may be side effects that are not yet known. The most common side effect, reported in other studies, is hyperkalemia (increase of potassium in the blood) that could cause:

- **Screening:** the doctor will collect information on your health condition. You will also have medical tests and procedures to ensure that it is safe for you to take part in the study.
- **Taking the medication:** the study drug will be given to you in the form of tablets. You will take 1 tablet of the study drug every morning at approximately the same time each day, while at home.
- **Procedures:** throughout the study, you will give blood and urine samples. At several visits you will have other tests regarding blood pressure and heart activity.
- **When at home:** you will be asked to remember to take the tablet each day and, for many visits, to collect early-morning urine samples 2 to 3 consecutive days before the visit and on the day of the visit.
- **Your role:** it is your responsibility to attend all scheduled study visits and inform your study doctor about any new symptoms, changes in your health or medications. You must also let any other doctor you see know that you are taking part in this study.
- **Follow-up:** you will continue to be observed for 1 month after you stop taking the drug.

Expert safety review

- This study has been reviewed and approved by regulatory health authorities in your country.
- The study has also been reviewed and approved by an independent Research Ethics Committee or Institutional Review Board. This review helps make sure your safety, rights, and wellbeing are protected.
- The study doctor, the Sponsor, Independent Research Ethics Committee or Institutional Review Board may decide to stop the treatment with the study drug for safety reasons at any time.

Please see the Information Sheet for Participants for complete information on the study and potential side effects.

