

What will happen at the study center visits?



During visits to the study center, your health and your response to the study drug(s) will be assessed in various ways, including:

- A physical examination
- Measuring your blood pressure and heart rate
- Checking your heart activity (using both echocardiograms and electrocardiograms)
- Collecting blood and urine samples from you
- Measuring the amounts of fluid in your body (called bioimpedance spectroscopy)

In addition to the study center visits, you will be asked to collect some urine samples and measure and record your blood pressure, heart rate and body weight at home, using monitoring devices that will be provided to you; you will be asked to return these at the end of the study.

Why should I take part?



A clinical research study is an important step towards finding potential treatments for people with CKD.

If you decide to take part in the **ZENITH-CKD Study**, you will not only be helping researchers and physicians understand this condition better, but you will also be playing an important role in ongoing efforts to improve healthcare for other people.

How do I find out more?



If you would like to learn more about the **ZENITH-CKD Study**, please contact:

Study center:

Contact person:

Address:

Telephone:

Email:

Contacting us does not mean that you must join the **ZENITH-CKD Study** or that you will be able to participate.

THE ZENITH-CKD STUDY:

A Clinical Research Study
for People with CKD

Patient Information
Brochure

ZENITHCKD

ZENITHCKD

What are clinical research studies?



Clinical research studies are carried out to discover whether investigational drugs:

- are safe to take
- have any side effects
- can help to reduce the signs and symptoms of an illness or prevent it from getting worse.

What is the ZENITH-CKD Study?



The **ZENITH-CKD Study** is looking at whether two investigational study drugs, used separately or combined, are safe and effective for people with chronic kidney disease (CKD). The two study drugs being investigated are **zibotentan** and **dapagliflozin**.

Who can take part in the study?



You may be able to take part in the **ZENITH-CKD Study** if you:

- are 18 years or older
- have a diagnosis of CKD
- have a body mass index (BMI) of ≤ 40 kg/m².

There are other criteria that need to be met before you can join the **ZENITH-CKD Study**; the study team will discuss these with you.

How many people will take part in the ZENITH-CKD Study?



Around **660 people** with CKD will take part in around 200 study centers across North and South America, Africa, Asia/Pacific, and Europe.

How long will I be in the study?



Individual participation in the study is expected to last between **17–19 weeks** in total, and includes the following parts:

Screening period (around 4 weeks):

- At an initial study center visit (Visit 1) the study team will test to see if you can take part in the study.

Study Treatment period (12 weeks; 6 study center visits):

- At the start of the Treatment period (Week 0/Visit 2) you will be assigned to your study treatment group.
- You will be required to take the assigned study drugs once a day, every day.
- You will have some tests and assessments at the study center visits.

Safety Follow-up period (2 weeks; 1 study center visit):

- At Week 14 (or 2 weeks after your last dose of study medication) the study team will check to see how you are doing; this will involve some final tests and assessments.

Which study drugs will I receive?

You will be randomly assigned (like pulling straws out of a hat) to one of the following four study treatment groups (at various doses):

- zibotentan alone
- dapagliflozin alone
- zibotentan + dapagliflozin
- placebo*



*Placebo looks like the other study drugs, but it contains no active ingredients.

You cannot choose which study drugs you receive; neither you nor the study team will know which study drugs you are taking. There will be no charge for any study-related treatment or care.

How will I take the study drugs?



All assigned study drugs will be given as either tablets or capsules. You will take one tablet and one capsule each day. The assigned study drugs should be taken with water, once a day, in the morning. You will be required to record the time you took the study drugs using the hand-held electronic diary you were given for this study.