

What are some of the risks and benefits of joining a clinical trial?

There are risks and benefits to joining any clinical trial. The trial doctor will explain the potential risks and benefits of being in this trial. During a trial, researchers may learn more about how well an investigational medication works. They also may learn about possible safety risks. Researchers do not always know all the possible side effects of an investigational medication.

Before joining a clinical trial, you should consider all risks and benefits. Gather as much information as possible before making your decision. You may want to speak to your regular doctors about possible treatment options. You may also want to speak with family members or close friends to help you decide.

How are clinical trial participants protected?

Before a trial can begin, a review board must review and approve the trial. This group is called an Institutional Review Board (IRB). An IRB is made up of doctors, scientists, and members of the community. The IRB reviews the trial to make sure that the trial follows the rules to help protect the rights, safety, and well-being of people who volunteer for a clinical trial. These rules make sure trials follow strict scientific and ethical guidelines.

Is there a cost to take part?

No, there is no cost for the trial treatment or the trial-related medical tests and exams.

More information

Thank you for your interest in this clinical trial. To learn more and see if you qualify, please contact:



Learn about a clinical trial for adults with

CHRONIC HEART FAILURE

You may qualify if you have a type of heart failure where your heart has less strength than normal to pump blood to your body, and if you have not recently been hospitalized for your heart failure or experienced a worsening of your heart failure that required urgent treatment.



What is a clinical trial?

A type of research designed to learn more about how our bodies respond to medicines or other treatments.

What is the purpose of this clinical trial?

In this clinical trial, doctors will test an investigational drug to learn:

- How safe it is
- How well it works to lower the risks of heart failure, including:
 - Being hospitalized with heart failure that is getting worse
 - Dying because of heart and blood vessel problems

Who can join?

You may be able to join this trial if you:

- Are at least 18 years old
- Are getting treatment for the type of heart failure where the heart has less strength than normal to pump blood to the body
- Have not gotten diuretics in an IV (water medicine in a vein) in the last 3 months as an outpatient
- Have not stayed in a hospital for heart failure in the last 6 months
- Are not waiting for a heart transplant

The trial doctor or staff will tell you about other rules to qualify for this trial and answer your questions.

What treatment is this trial testing?

The investigational drug has been approved for some types of heart failure but not the type of heart failure that we are investigating in this trial.

This trial is comparing the investigational drug to a placebo, which is a look-alike pill that contains no real, active medicine. Both the investigational drug and placebo are a tablet taken by mouth 1 time a day.

If I join, what trial treatment will I get?

You will first have medical tests to see if you qualify. If you qualify, you will be randomly assigned (like flipping a coin) to take the investigational drug or a placebo. You, the trial doctor, and the trial staff will not know if you are taking the investigational drug or a placebo.

You will also continue to take your current medicines for heart failure during the trial.

What will happen in this trial?

The total number of visits and the length of time you are in the trial depends on when you start the trial:

- You will have at least 6 visits at the trial clinic
- You can expect to take part for about 2 years. However, your time could last less than that, or could last more – up to about 3 years.

This trial has 3 parts:

- 1 Screening period** – 1 day or more.
You will first give informed consent to take part in the trial. To see if you qualify, you will:
 - Answer questions about your medical history and have medical tests such as:
 - Physical exam
 - Vital signs such as pulse rate, blood pressure, and weight
 - ECG (electrocardiogram) to check your heart's electrical activity
 - Blood test
 - Pregnancy test – if you are a woman able to have children
- 2 Trial treatment period** – about 2 years.
You will:
 - Take your investigational treatment 1 time a day
 - Have at least 6 visits at the trial clinic for the same medical tests and exams listed above, plus short surveys
- 3 Follow-up contact** – 1 day. About 14 days after your last trial treatment, you will:
 - Have a review of your medicine and side effects
 - Get a pregnancy test if you are a woman able to have children