

## What is a clinical trial (research study)?



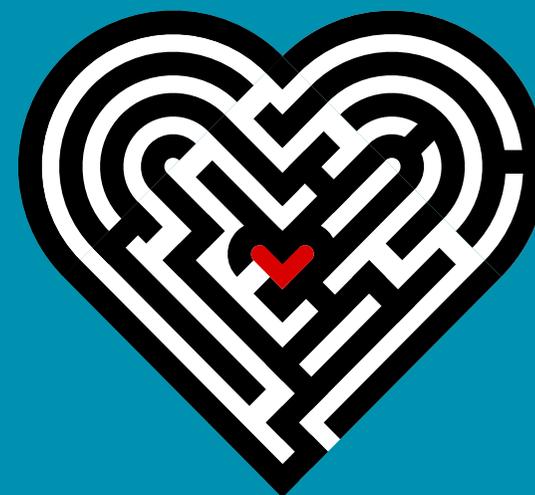
This study involves research. Taking part in a clinical research study is not the same as having regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to collect information about a medical intervention. Your participation in this study is voluntary (not required). If you decide not to take part in this study, you can continue with your current medical care.

DIAMOND

Thank you for your interest  
in the DIAMOND study.

For more information, please contact:

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Are you aware of the possible  
**complications of heart  
failure medications?**



Information for people interested in the  
DIAMOND study for the management of  
hyperkalemia (high blood potassium) in adults  
taking certain medications for heart failure

**Protocol number: PAT-CR-302**

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## Introduction

Certain heart failure medications may cause you to hold onto dangerously high amounts of potassium—a condition called hyperkalemia. If your doctor has changed your heart failure medication or mentioned your potassium risk, you may be eligible for the DIAMOND study. This study is researching a study drug called patiomer, which is already approved for treating hyperkalemia.

Thank you for considering enrollment in this important study.

## What is the purpose of this study?

The main purpose of this study is to learn if taking patiomer may help you to continue taking your heart failure medicines without developing hyperkalemia, and therefore may help you to live a longer life with fewer hospitalizations from heart failure.

In this study, patiomer will be compared to placebo. Placebo is a substance that is similar to the study drug but has no active medication in it.

## Who can participate in this study?

To be eligible for this study, you must:

- Be at least 18 years of age or older
- Be diagnosed with heart failure
- Have been hospitalized (or treated in an emergency room or outpatient visit) within the last 12 months due to heart failure
- Have or have had high potassium (hyperkalemia) as a side effect of your heart failure treatment

This is not a complete list of study requirements. Your study doctor will go over other study requirements with you to confirm if you qualify.

## How long will the study last?

You should expect to be in this study between 9 and 33 months (almost 3 years), and you will have between 13 to 20 study visits during this time. Your participation in this study is completely voluntary. You may withdraw from the study at any time and for any reason.

## What can I expect if I decide to participate?

The study is divided into 2 parts: a Run-in period and a Study Treatment period. During each study period, you will have 2 or more visits with your study doctor at the center. Each visit could last about 4 hours. You will also take your assigned study drug at home during your participation in the study. The study drugs include patiomer and placebo. All study participants will take patiomer at some point during the study, and some participants may take both patiomer and placebo during participation in the study. The study drugs are powder medications that are taken orally, by mixing the powder into water or juice and then drinking.

### Run-in period

- Lasts up to 12 weeks
- During the Run-in period, your study doctor will work to optimize your current heart failure treatment regimen, so your heart failure medications may change or increase in dose

### Study Treatment period

- This is a blinded study, which means that you will not know whether you are receiving patiomer or placebo. The study doctor and center staff involved in the study also will be blinded.
- All enrolled participants will have blood drawn over the course of the study
- Your study doctor will let you know how often you need to come to the clinic
- Lab tests, and other assessments will be performed during these visits
- At some of the study visits, you will fill out 2 questionnaires that ask about your symptoms and your physical and social functioning
- Not all activities will be performed at all visits

## What are my costs to take part in this study?

The study drug will be given at no cost to you, and you will not be charged for any study doctor visits, laboratory work, tests, or procedures that are needed for the study.

## What risks are involved if I decide to participate?

Any study has risks. These risks may include things that could make you sick, make you feel uncomfortable, or harm you. You might experience side effects related to the study drug (and rescue medication, if applicable) while participating in the study. If the study drug does not work for you, you may see an increase in your blood potassium level. There may be risks and side effects that are unknown. All drugs have a possible risk of an allergic reaction.

There are some known side effects of patiomer, such as:

- Constipation
- Diarrhea
- Abdominal pain
- Flatulence (gas)
- Nausea and vomiting
- Low magnesium in the blood

Taking blood from your arm may cause:

- Faintness
- Swelling
- Pain
- Redness
- Bruising
- Bleeding at the collection site
- Infection (infection rarely happens) where the needle is inserted

During electrocardiograms (ECG), or heart tests, skin irritation is rare but could occur during an ECG from the electrode patches or gel that is used.