

BaxDuo

PREVENT-HF

LET'S GET AHEAD OF IT TOGETHER

Explore this guide to learn more about our study and understand whether you'd like to take the next step with us

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This guide will tell you all you need to know about a new clinical study for people living with **type 2 diabetes (T2D)**, **cardiovascular disease** and **high blood pressure**.

Take your time to read through and remember to make a note of any questions so you can ask your doctor when you next see them.

What is a clinical study?

A clinical study is a type of medical research used to help doctors and researchers see how well a medicine works in people. It also explores whether a medicine has any side effects and if it works better than current treatments used to treat a condition.



Why have I been given this pamphlet?

People who live with the conditions that you live with are more likely to develop a health condition where the heart does not pump blood around the body as well as it should. The medical term for this is heart failure.

This may sound frightening, but we hope by helping you understand what we mean, you can work with your healthcare team to make the right decisions for you.

We understand living with chronic conditions can sometimes feel like you are on a health rollercoaster, and we definitely do not want to add to your burden. We just want you to be aware of this possibility. So, this pamphlet is designed to improve awareness of heart failure and empower you to take control of your health and future.

Our mission is to prioritize finding treatments that may help prevent heart failure before it happens. That's why we are carrying out a new clinical study in heart failure prevention called BaxDuo Prevent-HF.



So, what is heart failure?

We understand the term “failure” can sometimes bring up negative thoughts and feelings. After all, nobody really likes to think about failure in their everyday life.

And heart failure may sound alarming, but it doesn't mean that the heart is about to stop. It simply means that the heart doesn't pump blood around the body **as well as it should** and it may need some support to help it work better.

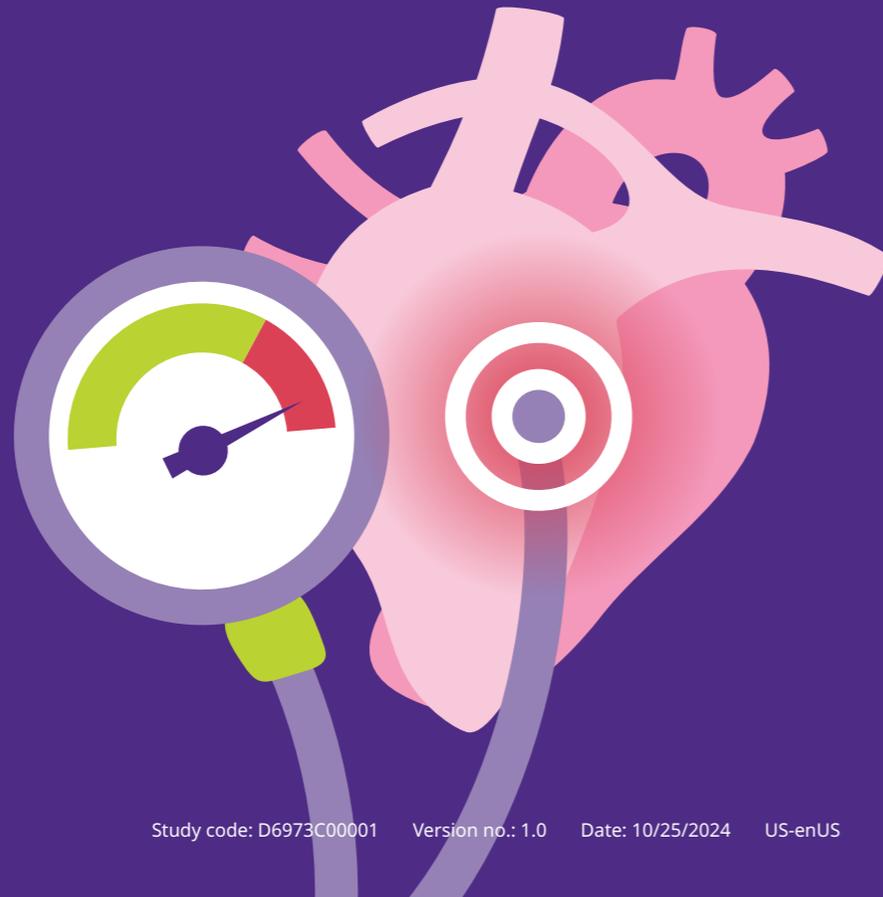
Our blood carries the nutrients and oxygen our bodies need to thrive. When the heart doesn't pump blood as well as it should, it lowers the amount of oxygen that can work in the body.

Make sure to have a conversation with your doctor about your heart if you are worried about any new symptoms.

How are T2D, high blood pressure and cardiovascular disease linked to heart failure?

Blood pressure is the force of your blood inside your blood vessels. When blood pressure becomes **too high**, it can put you at a greater risk of developing heart failure.

There are many reasons that blood pressure can become too high. But people living with T2D are more likely to develop high blood pressure.



Living with high blood pressure for a long time may also cause **cardiovascular disease**. Cardiovascular disease is a term used to describe a number of conditions that affect the heart and/or blood vessels. The conditions often result in the heart needing to **work harder** than normal.

Over time, high blood sugar levels from T2D, high blood pressure and cardiovascular disease can put **extra strain** on the heart and blood vessels and **increase the risk** of developing heart failure.

BaxDuo Prevent-HF has been designed to investigate whether a potential new combination of treatments may help to reduce this risk. You can find out more information about what is involved in the study as you read on.



What is BaxDuo Prevent-HF about?

BaxDuo Prevent-HF is looking at a combination of 2 drugs:

An **experimental** treatment called **baxdrostat**



An approved treatment for T2D, kidney disease and heart disease called **dapagliflozin**

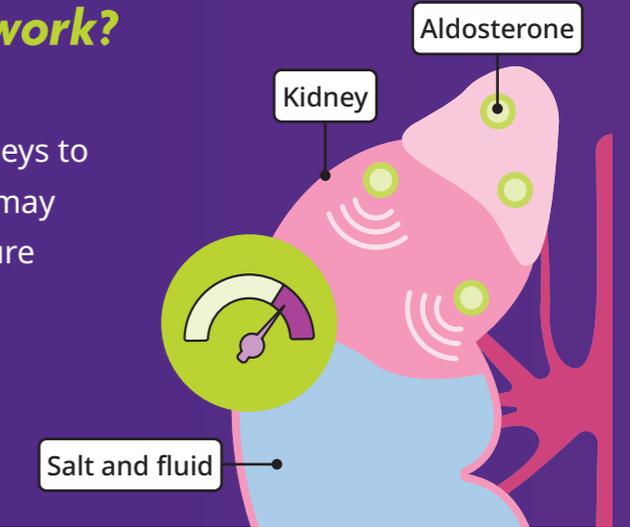


BaxDuo Prevent-HF is looking into whether baxdrostat and dapagliflozin can help to **prevent** the chance of developing heart failure.

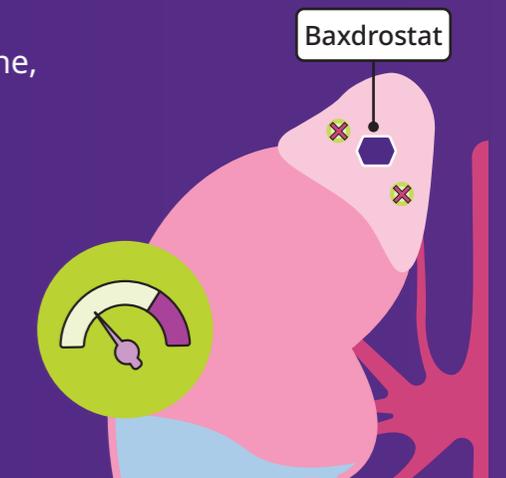
Our kidneys are a filter system for our bodies. They remove waste products and help to balance the level of fluid in the blood. Baxdrostat and dapagliflozin both work in the kidneys.

How does baxdrostat work?

1 Aldosterone tells your kidneys to store salt and fluid, which may increase your blood pressure

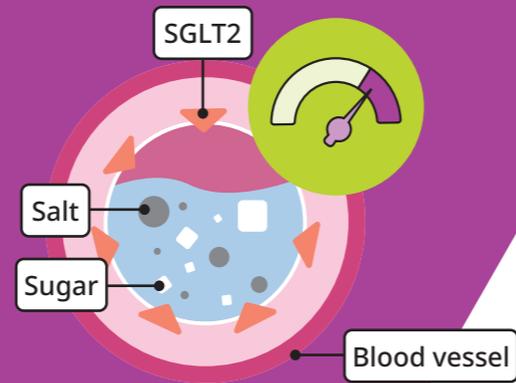


2 By reducing the levels of aldosterone, baxdrostat may help to lower your blood pressure

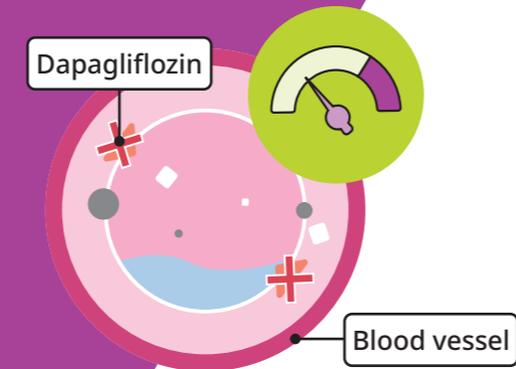


How does dapagliflozin work?

1 SGLT2 sends messages that increase the amount of sugar, salt and fluid in the blood. This can increase blood sugar levels and blood pressure



2 Dapagliflozin blocks SGLT2, which can help lower your blood pressure and sugar levels, and protect your heart from further damage



Baxdrostat and dapagliflozin are each taken as tablets, once per day. You may already be taking dapagliflozin (or another SGLT2 inhibitor) to treat your T2D or kidney disease.

We think these drugs may **work together** to lower your blood pressure and protect your kidneys more than dapagliflozin on its own.

One group of people in the study will get **baxdrostat** and **dapagliflozin**. The other group will get a **placebo*** and **dapagliflozin**.



Even if you are in the group that will receive placebo, you will still receive treatment with dapagliflozin throughout the study.

*The placebo will look the same as baxdrostat, but it will not contain baxdrostat or any other medicine. Placebos are used to help researchers find out if experimental treatments are working.

What can I expect if I take part?

If you do join BaxDuo Prevent-HF, you may take part for **around 3 years**, but this may be longer or shorter depending on when you join.

During the study, you will be asked to:



Take 2 study treatment tablets once a day



Come to **approximately 15 clinic appointments** to have some tests and assessments to check your health and well-being.

These may include:

- ✓ Physical exams and vital signs
- ✓ Blood and urine tests
- ✓ Heart tests
- ✓ Questionnaires about your day-to-day life, general well-being and how you are finding the study

Remember, taking part in a clinical study is always your choice, and you can stop at any time.

Taking part may mean:



Access to a potential new treatment (baxdrostat), which we think may help to lower your blood pressure and protect your heart



Frequent and detailed health checks



Helping to support how care moves forward for people with T2D and heart disease in the future

Don't forget, everyone taking part will receive dapagliflozin throughout the study.

Is there anything else I should know?



On the days of your clinic visits, you will need to make some adjustments to your daily routine. For at least 30 minutes before your visits, you will need to avoid:

- ✗ Exercise
- ✗ Smoking
- ✗ Drinking anything that contains alcohol or caffeine



As with all medicines, the study treatments may have some **side effects**. The study doctor can discuss these with you in detail and answer any questions you may have.



We do not know enough about the effect that the study treatments may have on an unborn child or child who is breastfeeding. If you are pregnant, breastfeeding or planning to become pregnant, you will not be able to take part in the study. This is to ensure that everybody can be kept as safe as possible.

Our goal

We understand you probably have a lot to already think about with the conditions you live with and receive care for.

Our goal is not to add to your worries, but to offer you clear and supportive information. We hope this helps you feel more confident and empowered as you work with your healthcare provider to make the care decisions that are right for you.



THANK YOU
for taking the time to explore whether you'd
like to take part in BaxDuo Prevent-HF.

If you'd like to find out more or feel our study is the right
fit for you, make sure to speak with your doctor.

Let's get ahead of it together



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