

**Clinical research study for people with excess weight who may also have heart disease or kidney disease, or both.**

## TRIUMPH-Outcomes



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**Are you looking to reduce your risk for heart disease and kidney disease, or both?**

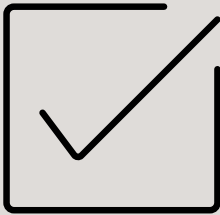


## Searching for ways to help people with excess weight.

Doctors and researchers are trying to find medicines that can help reduce the risk for heart disease and kidney disease in people with excess weight. Clinical research studies like the **TRIUMPH-Outcomes** study are an important part of this work.

This brochure will:

- explain the purpose of clinical research studies.
- help you decide if the **TRIUMPH-Outcomes** study might be right for you.



We hope this information will help you understand your options and take action.

If you have excess weight and also have heart disease or kidney disease, the **TRIUMPH-Outcomes** study may be for you.

## | What is a clinical research study?

A clinical research study is a medical study that helps to answer important questions about investigational medicines, such as:

- Is it safe?
- Does it work?
- Are there side effects?

All medicines must be tested in clinical research studies before they can be approved for doctors to give to patients. Without people taking part in these studies, we would not have new medicines.

The medicine that participants take in a clinical research study is called the study medicine. Different clinical research studies might have different types of study medicines.

**Study medicine** can be investigational medicine or placebo.

**Investigational medicine** means it is still being tested in clinical research studies.

**Placebo** looks the same as the investigational medicine but does not have any real medicine in it.

## | About the TRIUMPH-Outcomes study

Excess weight is a key risk factor for getting heart disease and kidney disease.

**Heart disease** is a condition that affects the heart and how it works. Heart disease can cause different problems, such as

- coronary artery disease
- stroke, or
- heart failure.

**Kidney disease** is a condition where, over time, the kidneys stop working as well as they should to remove waste from the body.

Researchers think that the investigational medicine being studied in the **TRIUMPH-Outcomes** study may help you to reduce your risk for these conditions.

The **TRIUMPH-Outcomes** study will include people with excess weight who also have

- heart disease
- kidney disease, or
- both heart disease and kidney disease.

## What is the TRIUMPH-Outcomes study and what does it involve?

The **TRIUMPH-Outcomes** study will test if the investigational medicine can help reduce the risk for heart disease and slow down the development of kidney disease in people with excess weight.

If you decide to take part in the **TRIUMPH-Outcomes** study, you will be randomly assigned (that is by chance) to get either the investigational medicine or placebo. You will give yourself an injection of the study medicine once a week using a prefilled single-dose pen.

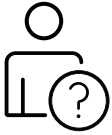
This study will last for around 5 years. You will have 27 planned study visits, and 1 final study visit.

The study may continue beyond 5 years until all the information needed has been collected.

The study will have around 10,000 participants from across the world.

## The TRIUMPH-Outcomes study has 3 main study periods

You may also have an optional pre-screening visit up to 8 weeks before the screening period.



### Screening period

Up to 8 weeks, 1 planned visit

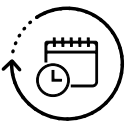
- To check if the study is right for you
- Screening activities may take more than 1 day to finish



### Study treatment period

About 5 years, 26 planned visits

- You will get the investigational medicine or placebo during this period.
- You will give yourself an injection of the study medicine once a week using a pre-filled single dose pen.
- If the study lasts longer than 5 years, you will have visits every 3 months until all information is collected.



### Final visit

Will occur when all information for the study has been collected, 1 planned clinic visit

- Final study health checks.

## | Why should I think about joining this study?

A medicine might work differently depending on other health conditions a person might have, and sometimes on their race, sex, and ethnicity.

It is important to test an investigational medicine in all people it is meant to help. This means we need a diverse group of people taking part in the clinical research study.

## | What are the possible benefits of taking part?

The benefits of taking part in the **TRIUMPH-Outcomes** study are:

- getting actively involved in healthcare research for people with excess weight, heart disease, and kidney disease
- helping others by advancing medical research

If you choose to take part, you will get at no cost to you:

- all study-related medicines
- all study-related care and check-ins
- access to specialized doctors and researchers.

**You do not need to have health insurance to take part in the TRIUMPH-Outcomes study.**

## Can I take part in this study?

**Yes**, you may be able to join the **TRIUMPH-Outcomes** study if you:

- Have a BMI of 27 kg/m<sup>2</sup> or more
- Are aged 45 years or older
- Have at least one of the following:
  - » Have heart disease
  - » Have kidney disease
  - » Have type 2 diabetes or not, and your HbA1c levels are equal to or less than 10 percent (86 mmol/mol)

**BMI** stands for **body mass index**. It is a number that compares a person's weight to their height. It can be used to tell if a person may be at risk of some health conditions.

## Can I change my mind about taking part?

Taking part in the **TRIUMPH-Outcomes** study is your choice. If you decide to take part, you may leave the study at any time for any reason.

**This study is from Eli Lilly and Company**

<https://e.lilly/47hoDyR>



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