



Who can take part?

You, or someone you know, may be able to take part if you/they:

- are 18 years of age or older **and have**
 - a body mass index of:
 - ◊ 27 kg/m² or more (overweight or obesity) and have a heart condition or
 - ◊ 30 kg/m² or more (obesity) and have a kidney condition **and/or**
 - at least 2 factors that put you/ them at risk of developing a heart condition, such as:
 - ◊ high blood pressure
 - ◊ high cholesterol
 - ◊ type 2 diabetes mellitus
 - ◊ a severe liver condition involving build-up of fats (called “NASH”).

There are additional requirements to be able to take part.

18⁺

18 years
of age or
older



What else do I need to consider?

- You may be reimbursed for reasonable time and travel costs during your participation. Please discuss this with the site staff for details.
- The trial has been approved by review boards which have been formally designated to protect the rights, safety, and well-being of the participants.



How do I get more information?

The site staff team will be happy to discuss the trial with you. To find out more, please contact the site staff team using the information provided here.



Trial participation is voluntary. By contacting us, you are under no obligation to take part in the trial.

Participant Information

RESEARCHING POTENTIAL NEW TREATMENTS FOR OBESITY

See if our obesity clinical trial is suitable for you

SYNCHRONIZE™ - CVOT



What is a clinical trial?

A clinical trial is a medical trial that helps to answer important questions about an investigational medication, such as:

- Does it work?
- What amount, or dose, may work best?
- How safe is it?
- Are there side effects?

All medications must be tested in clinical trials before they can be approved to be prescribed to patients. Without people taking part in these trials, we would have no new medications.

We plan to enroll a wide variety of participants. This is because medications used to treat overweight and obesity may affect people differently based on their age, sex, gender, and race/ethnicity.

Deciding to take part in a clinical trial is an important decision.

If you have any questions, you can contact the site staff team using the information provided in this brochure.



About the SYNCHRONIZE™-CVOT Trial

“Overweight” and obesity are complex, chronic (continuing for a long time) health conditions that can be caused by several factors, such as genetics, environment, hormones, or other medical conditions. Overweight and obesity cannot always be treated with only nutrition or physical activity changes because of the varied causes.

Overweight and obesity are **not**:

- ✗ just about food
- ✗ resolved with guilt or shame
- ✗ yours to manage alone
- ✗ cured by a miracle treatment.

The SYNCHRONIZE-CVOT Trial is testing an investigational medication to see if it is safe and whether it has any effect on the heart, blood vessels, and/or body weight. It is hoped the investigational medication may help lower blood sugar levels. Treating overweight and obesity can help prevent weight-related conditions such as type 2 diabetes mellitus and heart or liver disease, and improve quality of life.



What will taking part in the trial involve?

The investigational medication will be compared with a placebo, which looks the same but contains no active medication. You will have a 2-in-3 chance of receiving the investigational medication and a 1-in-3 chance of receiving placebo. The investigational medication and placebo will be referred to as the “trial medication” in this brochure.

You may be in the SYNCHRONIZE-CVOT Trial between 9 months and 27 months (2 years and 3 months). Your length of time in the trial depends on when you join and when researchers have collected enough information to understand the effects of the trial medication.



Screening period (about 3 weeks)

- You will visit the trial site to see if you want to take part, sign an Informed Consent Form, and check if the trial is right for you.



Trial treatment period (about 25 months, a little over 2 years)

- You will be asked to inject the trial medication yourself at home. You will receive training from the trial doctor or site staff. The amount (dose) of trial medication will change during the trial. It may be adjusted (increased or decreased) depending on whether or not you have side effects.
- You will visit the trial site every 1–3 months and have telemedicine visits (video calls) to check your health.
- You will meet with a nutritionist who will help set up an individualized nutrition and physical activity plan with you.

The number of visits you will have during this period depends on how long you are in the trial.



Follow-up period (about 3 weeks)

- You will have 1 follow-up visit for assessments, either at the trial site or at home, about 3 weeks after you have finished the trial treatment period.