Will my taking part in the study be kept confidential?

In this research trial we will use information from you and your medical records. We will only use information that we need for the research trial. We will let very few people know your name or contact details, and only if they need it for this trial. All staff involved in this trial will keep your data secure. We will also follow all privacy rules.

At the end of the trial, we will save some of the data in case we need to check it and use it for future research. We will make sure no-one can work out who you are from the reports we write.

The SOPHIST Trial

A Trial of the Effect of Sotagliflozin for Treating Patients with Type 1 Diabetes and Heart Failure Symptoms

The Participant Information Sheet tells you more about this.

The SOPHIST Trial

If you are interested in taking part or would like any more information, please contact the trial team by:

Calling Researcher:

[LOCAL RESEARCHER]

Or

E-mail: [LOCAL RESEARCHER]

We will discuss the trial further and send you a full information sheet.

Your local Investigator for the trial is:

Principal Investigator:
[LOCAL PI]
[ADDRESS]
[PHONE NUMBER]
[EMAIL]

LOCAL NHS LOGO

SOPHIST

SOtagliflozin in Patients with Heart Failure Symptoms and Type 1 Diabetes

A Trial of the Effect of Sotagliflozin for Treating Patients with Type 1 Diabetes and Heart Failure Symptoms

Do you have type 1 diabetes and either heart failure or any other heart conditions, symptoms such as breathlessness or fatigue, or take a water tablet?

Do you use a continuous glucose monitor?

You may be able to take part in a research trial.

University of Dundee

tctu

What is the trial about?

We are doing this trial to see if a tablet called sotagliflozin, a Sodium-glucose Cotransporter (SGLT) inhibitor, can improve quality of life in people with type 1 diabetes and heart failure (HF).

People with type 1 diabetes sometimes develop heart changes known as HF. People with HF can have symptoms like breathlessness, tiredness or ankle swelling, reduced quality of life and it can lead to hospital admission or fatal consequences.

SGLT inhibitors can reduce the chances of people developing HF. They can also improve patients' quality of life and reduce the chance of people with HF being admitted to hospital or dying. However, people with type 1 diabetes and HF were not in any of the trials carried out with SGLT inhibitors (people with type 2 diabetes were included).

We will compare people who take sotagliflozin tablets with people who take placebo tablets, which is a dummy tablet which looks the same as sotagliflozin. If we find that sotagliflozin improves quality of life in people with type 1 diabetes and HF then we might use sotagliflozin to treat people like you in the future.

What is involved?

Participation in the trial is entirely voluntary and you may withdraw at any time.

For the trial you will be asked to attend the hospital 5 times over a 4-month period. You will also have 3 phone or video calls with the research team. Taxi transport can be arranged, or travel expenses refunded for the visits.

At each visit you will be seen by a Researcher. During these visits the Researcher will do a simple health check, monitor your symptoms, and review your blood sugar and ketone levels. You will have some blood and urine samples collected. You will also be asked to complete questionnaires and may have a heart scan.

You will be given either sotagliflozin or placebo tablets to take, 1 per day for 4 months.

You will not be able to choose whether you take sotagliflozin or placebo. This will be decided randomly and neither you, nor your research team will know which tablet you are taking until after the trial is complete.

What are the possible benefits of taking part?

By taking part you are contributing to medical science. The results may help other people in the future.

What are the possible disadvantages and risks of taking part?

There is a small risk of developing diabetic ketoacidosis (DKA) or low blood sugar levels. If untreated both can make you very unwell. We will give you information to help prevent DKA or hypos happening.

We will ask you to measure your blood sugar and ketone levels regularly and review these and your insulin dose with you at each visit to reduce the chance of developing DKA or low blood sugars. We will advise you on any changes you should make to your insulin dose and any other medications you take.

Who has reviewed the study?

The Leeds West Research Ethics Committee has reviewed this trial.