

[Address]

[Date]

SOPHIST Trial

Sotagliflozin in Patients with HearFailure Symptoms and Type 1 Diabetes

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

Dear [PARTICIPANT NAME],

We are carrying out a research trial to see if a diabetes medication called sotagliflozin can help prevent heart failure (HF) and help improve symptoms of HF if they develop.

Patients who have type 1 diabetes can sometimes develop heart failure (HF). People with HF can have symptoms like breathlessness, tiredness or ankle swelling which can reduce quality of life and lead to being admitted to hospital, or in the worst-case scenario dying. There have been improvements in the treatment of heart failure, but there are still things we can improve to help patients live longer, prevent hospital admissions, and improve quality of life.

We are inviting you to take part in this trial because you have type 1 diabetes and have been diagnosed with heart failure, have heart changes on your echo scan that can sometimes lead to heart failure or have other medical conditions that can sometimes lead to heart failure.

Each participant will be given sotagliflozin tablets or placebo (dummy) tablets to take once per day for 4 months. In total you will have to attend the hospital 5 times in a 6-month period. All the visits will be at [LOCAL HOSPITAL]. You will also have 3 phone calls with us during this 6-month period.

To be in the trial you will need to be using a continuous glucose monitor.

If you take Sotagliflozin already or other similar drugs, you will not be able to take part. The research doctor will check this with you.

You will not be able to take part if you are pregnant, breastfeeding or planning a pregnancy.

Your participation is completely voluntary. If you choose to take part, you can stop the trial at any time and the medical care you get and your relationship with the medical or nursing staff looking after you won't be affected.

I have enclosed a brief Participant Information Sheet describing the trial in more detail and would be grateful if you would take the time to read it and consider taking part. If you are interested in taking part or would like to ask further questions, please contact the trial team using the details below. We will then provide you with a Participant Information Sheet which will describe the trial in full.



Call on [RESEARCH NURSE TELEPHONE NUMBER]



Return the attached REPLY SLIP in the SAE



E-mail: [RESEARCH NURSE EMAIL]

With kind regards,

[PI/GP NAME]

[JOB TITLE]

REPLY SLIP

Please complete the details below and return in the enclosed envelope.

Initials

I am interested in taking part in the SOPHIST Trial and I agree to be contacted by a member of the trial team.

I agree to a member of the trial team looking at my medical records to confirm if I am likely to be suitable for the trial

Any identifiable information you provide here will be held securely by [SITE] in accordance with the UK Data Protection Act 2018. This information will only be used by your local trial team.

Name:

Address:

Telephone No:

Mobile No:

E-Mail Address:

Preferred method of contact:

Date:

Thank you for your interest in the SOPHIST Trial