LOCAL NHS LOGO

☎
Email address:

SOPHIST – SOtagliflozin in **P**atients with **H**eart fa**i**lure **S**ymptoms and **T**ype 1 Diabetes

A phase 2 double-blind randomised controlled trial studying the effect of sotagliflozin 200mg once daily versus placebo in individuals with heart failure symptoms and type 1 diabetes on quality of life measured using the Kansas City Cardiomyopathy Questionnaire**.**

Dear Colleague,

Your patient has kindly consented to join the SOPHIST Trial.

Patient details
Name: _____
DOB: _____

Address: _____
_____
_____

The SOPHIST Trial is a multi-center, randomised, placebo-controlled trial investigating if sotagliflozin can improve quality of life in people with type 1 diabetes and heart failure symptoms. In addition, this trial will also assess the safety and tolerability of sotagliflozin in this population.

This trial aims to recruit 320 people with type 1 diabetes and heart failure symptoms in multiple sites in the UK. Participants will be randomly allocated to one of two groups (sotagliflozin or placebo) and both the research team and participants will be blinded to allocation.

Participants will be in the trial for approximately 6 months and will be given sotagliflozin 200mg or placebo 200mg tablets to take 1 per day for 4 months. Participants will be seen prior to beginning their medication, and then for 5 further visits after this point. At all visits the participants glucose management and insulin requirements will be reviewed. Participants with a HbA1c <58mmol/mol will have a 10% insulin dose reduction prior to taking their first dose of sotagliflozin/placebo.

Participants taking sotagliflozin are at higher risk of developing DKA and hypoglycaemia, all participants will be given information on how to prevent, recognise and treat DKA and hypoglycaemia prior to receiving their first dose of sotagliflozin/placebo. There is also an increased risk of dehydration and hypotension to patients already on diuretics. The trial medication should be temporarily stopped if a participant develops a complicated urinary tract infection.

If your patient consents, you will be informed of any significant clinical findings found during your patient's participation in this trial and any relevant corrective action implemented by myself or medical colleagues.

If you have any questions, please do not hesitate to contact me.

Thank you for your assistance.

With kind regards,

[PI name]
[PI tel]
PI email]