Visits

All visits

Participant Transport

- Participants should be offered a taxi to bring them to the appointment and return them home. This has been proven to help recruitment and retention of trial participants.

- An account should be set up with a local taxi company for this as per local practice.

- Alternatively, participants wishing to use public transport should have their actual cost reimbursed or petrol paid. This should be done as per local procedure e.g. from petty cash or by completing a travel expense form.

All visits

Participant Identity

Participant identity should be checked at each visit. Some examples of identification are listed below:

- Passport.
- Driving licence.
- Current matriculation card.
- Young person’s or senior citizen’s railcard.
- Proof of Address.
- National Insurance Card.
- CHI Number/Medical Card.

All visits

Participant trial ID

- All participants consented to the trial should be allocated a participant ID number and recorded on the enrolment and randomisation log.
- Participant ID numbers are made up of five numbers:
  - First two numbers indicate the site
  - Last three indicate the participant number at that site.

  E.g. 01-001 is the first participant at site one.
- Use participant ID numbers in order.
- Ensure site ID is correct for your site.
- If participant fails screening, and does not go on to randomisation, their participant ID number should not be re-used.

All visits

Informed Consent

- Informed consent should be obtained at visit 1 prior to initiating any research activities.
- Verbal confirmation of continued consent should be undertaken at all subsequent visits.

Worksheets

- Worksheets will be provided to facilitate data collection but their use is not mandatory.
- If worksheets are used to record source data, they must be filed in the medical notes.

Visit timelines/assessments

- Missed trial assessments or visits completed outside the visit window will not be reported as breaches where this is due to participant choice or a clinical decision.

All visits	Visit 1 (Screening)	Visit 2	Visit 3 (Baseline)	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8
	-30 days to -14 days	-7 days +/- 3 days	Day 0	Week 1 +/- 3 days	Week 4 +/- 3 days	Week 10 +/- 3 days	Week 16 +/- 3 days	Week 20 +/-3 days
	Research Site	Research Site	Research Site	Remote/ Research Site	Research Site	Remote/ Research Site	Research Site	Remote/ Research Site
Informed Consent	X							
Eligibility	X		X					
Demographics/Medical History	X							
NYHA Class	X						X	X
Record Concomitant Medications	X	X	X	X	X	X	X	X
Adverse Events		X	X	X	X	X	X	X
Weight	X		X				X	
Height, Waist and hip circumference	X							
Blood Pressure & pulse	X		X				X	
Physical Examination	X						X	
ECG	X							
Echocardiography (LVEF) if not available within 24 months.	X							
Education/Review of Glucose Management and ketones / documentation of glucose and ketone readings / documentation of hypoglycaemic and DKA events		X	X	X	X	X	X	X
Registration with CGM app (if not already signed up), optional		X						
Documentation of summary Data and/or glucose readings from CGM, from previous 2 weeks			X		X		X	
Kansas City Cardiomyopathy Questionnaire (KCCQ)	X		X		X		X	
Diabetes Treatment Satisfaction Questionnaire (status at baseline, change+status at 16-weeks)			X				X	
EQ-5D-5L Questionnaire			X				X	
6 minute-walk test			X				X	
Urine pregnancy test	X		X					
Safety Bloods (FBC, U&E, LFT, glucose)	X		X		X		X	
HbA1c	X						X	
NT-proBNP or BNP (local) within 12 months of screening	X							
Research blood sample (NT-proBNP for central lab analysis in Dundee)			X				X	
Research blood sample (C-peptide for central lab analysis in Dundee)			X					
Urine albumin, creatinine, sodium			X		X		X	
Additional research blood samples			X				X	
Additional research urine samples			X				X	
Randomisation			X					
Dispensing of IMP			X					
Compliance to IMP				X	X	X	X	
IMP Accountability			X				X	

Visit 1 – Day -30 to -14, Screening (approx. 3 hours) at Research Site

- Informed consent.
- Demographics and medical history including concomitant medication check.
- NYHA Class.
- Blood pressure and pulse.
- Height, weight, waist and hip circumferences.
- Physical examination (doctor) and documentation of average daily basal and bolus insulin doses for previous 7 days.
- ECG.
- Echocardiography (LVEF) if cardiac imaging test not available within 24 months.
- Urine pregnancy test for women of childbearing potential.
- Full blood count, urea & electrolytes, liver function tests, glucose and HbA1c (local NHS labs).
- NT-proBNP or BNP (local NHS labs) if not available within 12 months of screening.
- Kansas City Cardiomyopathy Questionnaire.

- ECG, echo and all NHS lab results to be reviewed by doctor on Delegation Log.
- Where an ineligible participant's medical condition or concomitant medications change sufficiently so that they are deemed potentially eligible for the trial, they may be rescreened.
  - Must receive a new copy of the PIS, be re-consented and given a new Participant ID number.
- Details of **all** participants **consented** to the trial must be recorded on the Enrolment and Randomisation Log.

Visit 2 – Day -7 (± 3 days), at Research site (approx. 30 mins)

- Concomitant medication check.
- Adverse event recording.
- Review/education of glucose and ketone management.
- Documentation of hypoglycaemic and DKA events as well as glucose and ketone readings.
- Registration with app (e.g. Libreview/Clarity) if not already signed up, optional.

Visit 3 – Day 0 (i.e. Up to 30 days after visit 1), Baseline (approx. 2 hours)

- Inclusion/exclusion criteria check.
- Adverse event recording and concomitant medication check.
- Weight, blood pressure and pulse.
- Urine pregnancy test for women of childbearing potential.
- Review/education of glucose and ketone management.
- Documentation of hypoglycaemic and DKA events, glucose and ketone readings and average daily basal and bolus insulin doses for previous 7 days.
- Documentation of CGM summary data for previous 14 days.
- Questionnaires (i.e. KCCQ, DTSQs and EQ-5D-5L).
- 6 minute-walk test
- Full blood count, urea & electrolytes, liver function tests and glucose (local NHS labs).
- Research blood samples.
- Urine albumin, creatinine, sodium.
- Research urine sample, if consented for additional samples.
- Eligibility confirmed by delegated doctor.
- Randomisation.
- Dispensing/accountability of IMP.

- All NHS lab results must be reviewed by doctor on Delegation Log
- Eligibility to be assessed once all test results have been reviewed.
- Assessment of eligibility must be carried out by doctor on Delegation Log.

Visit 4 – Week 1 (± 3 days), Remote/Research Site (approx. 45 min)

- Concomitant medication check.
- Adverse event recording.
- Review/education of glucose and ketone management.
- Documentation of hypoglycaemic and DKA events as well as glucose and ketone readings.
- Compliance with treatment.

Visit 5 – Week 4 (± 3 days), at Research Site (approx. 45 min)

- Concomitant medication check.
- Adverse event recording.
- Review/education of glucose and ketone management.
- Documentation of hypoglycaemic and DKA events as well as glucose and ketone readings.
- Documentation of summary data and/or glucose readings from CGM, from previous 2 weeks.
- Questionnaire (i.e. KCCQ).
- Full blood count, urea & electrolytes, liver function tests and glucose (local NHS labs).
- Urine albumin, creatinine, sodium.
- Compliance with treatment.

Visit 6 – Week 10 (± 3 days), Remote/Research Site (approx. 45 min)

- Concomitant medication check.
- Adverse event recording.
- Review/education of glucose and ketone management.
- Documentation of hypoglycaemic and DKA events as well as glucose and ketone readings.
- Compliance with treatment.

Visit 7 – Week 16 (± 3 days), Research Site (approx. 2 hours)

- Adverse event recording and concomitant medication check.
- Weight, blood pressure and pulse.
- NYHA Class.
- Physical Examination.
- Review/education of glucose and ketone management.
- Documentation of hypoglycaemic and DKA events, glucose and ketone readings and average daily basal and bolus insulin doses for previous 7 days.
- Documentation of CGM summary data for previous 14 days.
- Questionnaires (i.e. KCCQ, DTSQs, DTSQc and EQ-5D-5L).
- 6 minute-walk test.
- Full blood count, urea & electrolytes, liver function tests, glucose and HbA1c (local NHS labs).
- Research blood samples.
- Urine albumin, creatinine, sodium.
- Research urine sample, if consented for additional samples.
- Compliance with treatment.
- IMP accountability.

Visit 8 – Week 20 (± 3 days), Remote/Research Site (approx. 45 min)

- Concomitant medication check.
- Adverse event recording.
- NYHA Class.
- Review/education of glucose and ketone management.
- Documentation of hypoglycaemic and DKA events as well as glucose and ketone readings.