19. Visit 3 - Baseline - Date of Visit 3 - Baseline

Number	Question	Answers
19.1	Date of Visit 3 - Baseline	*(dd-mm-yyyy)*
19.2	Is Date of Visit 3 between 4 and 10 days after Date of Visit 2?	**Automatic Calculation on Castor**

20. Visit 3 - Baseline - Weight

Number	Question	Answers
20.1	Weight	kg

21. Visit 3 - Baseline - Concomitant Medications

Number	Question	Answers
21.1	Concomitant Medications	
	Please complete Concomitant Medications Log	

22. Visit 3 - Baseline - Adverse Events

Number	Question	Answers
22.1	Adverse Events	
	Please complete Adverse Events Log	

23. Visit 3 - Baseline - Glucose Review

Number	Question	Answers
23.1	Was Glucose Management Assessed? *If Glucose Management not assessed, this is a Protocol breach*	○ YES ○ NO
23.2	Insulin administration	○ Subcutaneous injections ○ Pump
23.3	Daily basal insulin dose (average of last 7 days)	..... units/day
23.4	Daily bolus insulin dose (average of last 7 days)	..... units/day
23.5	Total daily insulin dose (average of last 7 days)	**Automatic Calculation on Castor**
	CGM summary data from previous 2 weeks	
23.6	Are summary data from CGM readings over the 2 weeks prior to this visit available?	○ YES ○ NO
23.6.1	Number of days CGM worn over preceding 14 days	..... days
23.6.2	Percentage of time CGM was active over preceding 14 days	..... %

23.6.3	Mean blood glucose level over preceding 14 days		mmol/L
23.6.4	Blood glucose percentage time above 13.9 mmol/L over preceding 14 days		%
23.6.5	Blood glucose percentage time from 10.1 to 13.9mmol/L over preceding 14 days		%
23.6.6	Blood glucose percentage time from 3.9 to 10.0 mmol/L over preceding 14 days		%
23.6.7	Blood glucose percentage time from 3.0 to 3.8 mmol/L over preceding 14 days		%
23.6.8	Blood glucose percentage time below 3.0 mmol/L over preceding 14 days		%
23.6.9	Do blood glucose percentage times spent in each range add up to 100%?	**Automatic Calculation on Castor**	
23.6.10	Glycaemic variability index over preceding 14 days		%CV

23.1.1	Does the participant report any level 2 or level 3 hypoglycaemic events since last visit? *If there has been a level 3 hypoglycaemic event since last visit, participant is ineligible for trial. Complete the hypoglycaemic repeating data.*	○ YES ○ NO

Level 3 hypoglycaemic event is defined as requiring hospitalisation and/or assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions. These episodes may be associated with sufficient neuroglycopaenia to induce seizure or coma. Plasma glucose measurements may not be available during such an event, but neurological recovery attributable to the restoration of plasma glucose to normal is considered sufficient evidence that the event was induced by a low plasma glucose concentration

Hypoglycaemic Events

23.1.1.2	**Please record any level 2 or 3 hypoglycaemic events in the Hypoglycaemic Events Log**	
23.1.3	Does the participant report any other symptomatic hypoglycaemic events in the last 2 weeks?	○ YES ○ NO
23.1.3.1	If Yes, specify	
23.7	HbA1c performed?	**Automatic Calculation on Castor**
23.7.1	HbA1c units used?	**Automatic Calculation on Castor**
23.7.2	HbA1c level	**Automatic Calculation on Castor**
23.7.1.1	Is HbA1c result lower than 58 mmol/mol or 7.5%?	**Automatic Calculation on Castor**
23.7.1.2.1	If HbA1c result is lower than 58 mmol/mol or 7.5% was insulin reduced by 10%? *If insulin not reduced by 10%, this is a Protocol breach*	○ YES ○ NO

24. Visit 3 - Baseline - Ketone Review

Number	Question	Answers
	Ketone Readings	
24.1	Have there been Ketone measures since the last visit?	○ YES ○ NO
24.1.1	Number of ketone measurements taken since last visit	
24.1.2	Number of episodes with ketone levels between 0.6 and 1.5 mmol/L (inclusive of endpoints).	
	A distinct episode is a period where ketones have gone above the threshold (0.6mmol/L) and then come down below this, If it then went up again that would be a new distinct event.	
24.1.4	Number of episodes with ketone levels greater than 1.5 mmol/L	
	A distinct episode is a period where ketones have gone above the threshold (1.5mmol/L) and then come down below this. If it then went up again that would be a new distinct event.	
24.1.6	Have there been any DKA events since the last visit?	○ YES ○ NO
	If there has been a DKA event since last visit, participant is ineligible for trial. Complete the DKA Log.	
	DKA Events **If the participant has experienced any DKA events please complete the DKA Events Log.**	

Repeating Data 'Vital Signs'

Form Vital Signs

Question	Answers
Blood Pressure - Systolic	mmHg
Blood Pressure - Diastolic	mmHg
Pulse	bpm

26. Visit 3 - Baseline - Questionnaires

Number	Question	Answers
26.1	Has the KCCQ questionnaire been completed?	◯ YES ◯ NO
26.1.1	Add KCCQ	**Performed in Castor**
26.2	Has the DTSQs questionnaire been completed?	◯ YES ◯ NO
26.2.1	Add DTSQs	**Performed in Castor**
26.3	Has the EQ-5D-5L questionnaire been completed?	◯ YES ◯ NO
26.3.1	Add EQ-5D-5L	**Performed in Castor**

27. Visit 3 - Baseline - 6-Minute Walk Test

Number	Question	Answers
	Please complete 6-Minute Walk Test	
27.1	Was 6-Minute Walk Test completed?	○ YES ○ NO
27.1.1	Distance walked in 6 minutes?	..... m
27.1.2	Number of stops?	.....

28. Visit 3 - Samples

Number	Question	Answers
28.1	**Safety Bloods**	
	Date of blood sample	[ ] [ ] [ ] *(dd-mm-yyyy)*
	Haemoglobin	[ ]
	Haemoglobin Unit	○ g/L ○ g/dL
	Sodium	[ ] mmol/L
	Potassium	[ ] mmol/L
	Urea	[ ] mmol/L
	Creatinine	[ ] µmol/L
	Glucose	[ ] mmol/L
	eGFR	[ ] mL/min/1.73m2

28. Visit 3 - Baseline - Samples

Number	Question	Answers
	Urine Pregnancy Test	
28.2	Pregnancy test performed	○ YES ○ NO ○ N/A
28.2.1	Pregnancy test result *Without a negative pregnancy test result, the participant is not eligible to take part in the trial.*	○ Positive ○ Negative
28.2.2	Is the participant either permanently sterilized or post-menopausal?	○ YES ○ NO
	Urine Sample	
28.3	Urine Sample	

Repeating Data 'Urine Sample'

Form Urine sample

	Question	Answers
	Date of urine sample	[ ] [ ] [ ] *(dd-mm-yyyy)*
	Albumin	[ ] mg/L
	Creatinine	[ ] µmol/L or mmol/L
	Urine albumin/creatinine ratio	[ ] mg/mmol
	Sodium	[ ] mmol/L
28.4	Were research bloods taken and processed as per laboratory manual?	◯ YES ◯ NO
28.4.1	If answered No, give reason	

29. Visit 3 - Baseline - Inclusion Criteria

Number	Question	Answers
29.1	Age 18 years to <85 years	◯ YES ◯ NO
29.2	Type 1 Diabetes	**Automatic Calculation on Castor**
29.3	Insulin dose greater than or equal to 0.5 units/kg body weight at screening or BMI equal to or greater than 25kg/m2 at screening	**Automatic Calculation on Castor**
29.4	Using continuous glucose monitor at screening or willing to use one for the duration of the trial	**Automatic Calculation on Castor**
29.5	Diagnosis of heart failure (HF), defined as one or more of the following:	**Automatic Calculation on Castor**
	Previous HF hospitalisation where HF was documented as the primary cause of hospitalisation and there was a requirement for loop diuretics.	
	Impaired left ventricular function (i.e. LVEF <50% by any imaging modality) at any time.	
	Preserved LV systolic function (LVEF ≥50%) with left atrial enlargement (2-dimensional measurement of left atrial width ≥3.8cm or left atrial length ≥5.0 cm or left atrial area ≥20cm2 or left atrial volume index >29 ml/m2) within the last 24 months.	
	Preserved LV systolic function (LVEF ≥50%) with left ventricular hypertrophy (2-dimensional measurement of end-diastolic interventricular septal diameter ≥1.2cm or end-diastolic left ventricular posterior wall diameter ≥1.2cm) within the last 24 months.	
	Preserved LV systolic function (LVEF ≥50%) with diastolic dysfunction (septal e' <7cm/sec or lateral e' <10cm/sec or average E/e' ≥15) within the last 24 months.	
29.6	New York Heart Association Class II-IV at screening	**Automatic Calculation on Castor**
29.7	Elevated N-terminal pro-B-type natriuretic peptide (≥400 ng/L ◯ for those in atrial fibrillation/flutter, ≥250 ng/L for those in all other rhythms) or B-type natriuretic peptide (≥100 ng/L for those in atrial fibrillation/flutter, ≥75 ng/L for those in all other rhythms) within 12 months of screening	YES ◯ NO

29.8	Kansas City Cardiomyopathy clinical summary score less than 85 at screening.	**Automatic Calculation on Castor**

30. Visit 3 - Baseline - Exclusion Criteria

Number	Question	Answers
30.1	Cardiac surgery (coronary artery bypass graft or valve replacement), type 1 myocardial infarction, implantation of cardiac device (including biventricular pacemaker) or cardiac mechanical support implantation within 1 month of screening, or between screening and randomisation, or planned during the trial.	○ YES ○ NO
30.2	End-stage heart failure requiring left ventricular assist devices, intra-aortic balloon pump, or any type of mechanical support at the time of randomisation.	○ YES ○ NO
30.3	Documented primary severe valvular heart disease, amyloidosis or hypertrophic cardiomyopathy as principal cause of heart failure as judged by the local investigator.	○ YES ○ NO
30.4	Respiratory disease thought to be the primary cause of dyspnoea as assessed by the local investigator.	○ YES ○ NO
30.5	Chronic kidney disease with estimated glomerular filtration rate <25ml/min/1.73m2 at screening.	○ YES ○ NO
30.6	Moderate or severe hepatic impairment (e.g. Child-Pugh B and C) at screening as judged by the local investigator	○ YES ○ NO
30.7	Use of sotagliflozin or any SGLT2 inhibitor within 1 month of screening or between screening and randomisation.	○ YES ○ NO
30.8	Previous hypersensitivity/intolerance to SGLT2 inhibitors.	○ YES ○ NO
30.9	Presence of malignancy with expected life expectancy less than 1 year at screening	○ YES ○ NO

30.10	Severe hypoglycaemia (hospitalisation for hypoglycaemia or episode requiring external assistance to treat) within 1 month prior to screening or between screening and randomisation.	○ YES ○ NO
30.11	One episode of diabetic ketoacidosis or nonketotic hyperosmolar state within 1 month of screening or between screening and randomisation, or greater than or equal to 2 diabetic ketoacidosis or nonketotic hyperosmolar state events within 6 months of screening.	○ YES ○ NO
30.12	Pregnant or lactating women	○ YES ○ NO
30.13	Women of childbearing age or male partners of women of childbearing age and not practicing a method of acceptable birth control	○ YES ○ NO
30.14	On a ketogenic diet.	○ YES ○ NO
30.15	Unwilling/unable to share glucose and ketone monitoring data.	○ YES ○ NO
30.16	Use of any investigational drugs within five times of the elimination half-life after the last dose or within 30 days, whichever is longer. Current enrolment in non-interventional, observational studies will be allowed.	○ YES ○ NO

31. Visit 3 - Baseline - Eligibility

Number	Question	Answers
	Eligibility must be checked prior to randomisation by a doctor delegated this task in the Delegation Log.	
31.1	Is the participant eligible to take part in the trial?	○ YES ○ NO
31.2	Was eligibility signed off by a delegated doctor prior to randomisation?	○ YES ○ NO
31.3	Name of PI or delegated doctor	
31.4	Date of signature	*(dd-mm-yyyy)*
31.5	Date of signature between date of visit 3 and date of randomisation?	**Automatic Calculation on Castor**

32. Visit 3 - Baseline - Randomisation

Number	Question	Answers
32.1	Has the participant been randomised? *If field's value is equal to NO: Participant is not eligible for trial. Please complete a Completion of Trial/Withdrawal form.*	○ YES ○ NO
32.1.1	Date of Randomisation	[ ] [ ] [ ] *(dd-mm-yyyy)*
32.1.2	Is date of randomisation after date of consent (Visit 1) and on or after date of eligibility sign-off (Visit 3)?	**Automatic Calculation on Castor**

33. Visit 3 - Baseline - Dispensing of IMP

Number	Question	Answers
33.1	Was IMP dispensed at visit?	○ YES ○ NO
33.1.1	If answered No, give reason?	