Clinical trial results:
Low-Dose Dasiglucagon for Prevention of Insulin-Induced Hypoglycemia in People with Type 1 Diabetes

Summary

EudraCT number	2020-000551-12
Trial protocol	DK
Global end of trial date	04 January 2021

Results information

Result version number	v1 (current)
This version publication date	25 April 2022
First version publication date	25 April 2022

Trial information

Trial identification

Sponsor protocol code	72418

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04449692
WHO universal trial number (UTN)	-
Other trial identifiers	Regional Committee on Health Research Ethics: H-20013256

Notes:

Sponsors

Sponsor organisation name	Steno Diabetes Center Copenhagen
Sponsor organisation address	Borgmester Ib Juuls Vej 83, Herlev, Denmark, 2730
Public contact	Christian Laugesen, Steno Diabetes Center Copenhagen, +45 51642387, christian.laugesen@regionh.dk
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Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	01 November 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 January 2021
Global end of trial reached?	Yes
Global end of trial date	04 January 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study is to compare the efficacy of low-dose (80 and 120 µg) dasiglucagon to oral carbohydrate (15 g) consumption for prevention of s.c. insulin-induced hypoglycemia in people with type 1 diabetes.

Protection of trial subjects:

NA

Background therapy:

All participants used their regular treatment modality; 10 participants used insulin pump therapy and 10 participants used MDI therapy.

Evidence for comparator: -

Actual start date of recruitment	23 June 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	20
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from the outpatient diabetes clinic at Steno Diabetes Center Copenhagen from June 2020 to October 2020.

Pre-assignment

Screening details:

After providing oral and written informed consent, participants completed a screening visit for assessment of the eligibility criteria. Procedures included routine blood sampling, physical examination, review of medical history and medications as well as registration of baseline characteristics.

Period 1

Period 1 title	Study period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

The study was a partially single-blind study. The participants were not blinded to the dose of the two dasiglucagon interventions; however, they were not blinded to the oral glucose intervention.

Arms

Are arms mutually exclusive?	No
Arm title	15 g oral glucose (CHO)

Arm description:

15 g oral glucose (CHO) from dextrose tablets (Dextro Energy GmbH & Co. KG, Germany)

Arm type	Standard of care

No investigational medicinal product assigned in this arm

Arm title	80 µg s.c. dasiglucagon (D80)

Arm description:

80 µg dasiglucagon (D80) s.c. injection into a lifted skinfold of the abdominal wall.

Arm type	Experimental
Investigational medicinal product name	dasiglucagon
Investigational medicinal product code	
Other name	CAS15 number: 1544300-84-6, EV Substance code: SUB193123
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

80 µg dasiglucagon (D80)was administered at t=0 as a s.c. injection into a lifted skinfold in the abdominal wall.

Arm title	120 µg dasiglucagon (D120)

Arm description:

120 µg dasiglucagon (D120) s.c. injection into a lifted skinfold of the abdominal wall.

Arm type	Experimental
Investigational medicinal product name	dasiglucagon
Investigational medicinal product code	
Other name	CAS15 number: 1544300-84-6, EV Substance code: SUB193123
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

120 µg dasiglucagon was administered at t=0 as a s.c. injection into a lifted skinfold in the abdominal wall.

Number of subjects in period 1	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg dasiglucagon (D120)
Started	20	20	20
Completed	20	19	20
Not completed	0	1	0
Work-related reasons, not related to study	-	1	-

Baseline characteristics

Reporting groups

Reporting group title	Study period

Reporting group description: -

Reporting group values	Study period	Total	
Number of subjects	20	20	
Age categorical Units: Subjects			
Adults (18-64 years)	20	20	
Age continuous Units: years			
median	47		
full range (min-max)	23 to 64	-	
Gender categorical Units: Subjects			
Female	8	8	
Male	12	12	
Duration of type 1 diabetes Units: year			
median	19		
full range (min-max)	3 to 58	-	
Body mass index Units: kilogram(s)/square metre			
median	24.7		
full range (min-max)	21.6 to 36.4	-	
Total daily insulin dose Units: unit(s)			
median	35		
full range (min-max)	20 to 65	-	
HbA1c Units: percent			
median	6.8		
full range (min-max)	4.9 to 7.7	-	

Subject analysis sets

Subject analysis set title	15 g oral glucose (CHO)
Subject analysis set type	Full analysis
Subject analysis set description: 15 g oral glucose (CHO) intervention	
Subject analysis set title	80 µg s.c. dasiglucagon (D80)
Subject analysis set type	Full analysis
Subject analysis set description: 80 µg s.c. dasiglucagon (D80) intervention	
Subject analysis set title	120 µg s.c. dasiglucagon (D120)
Subject analysis set type	Full analysis

Subject analysis set description:
120 µg s.c. dasiglucagon (D120) intervention

Reporting group values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)
Number of subjects	20	19	20
Age categorical Units: Subjects			
Adults (18-64 years)			
Age continuous Units: years median full range (min-max)			
Gender categorical Units: Subjects			
Female	8	8	8
Male	12	12	12
Duration of type 1 diabetes Units: year median full range (min-max)			
Body mass index Units: kilogram(s)/square metre median full range (min-max)			
Total daily insulin dose Units: unit(s) median full range (min-max)			
HbA1c Units: percent median full range (min-max)			

End points

End points reporting groups

Reporting group title	15 g oral glucose (CHO)
Reporting group description:	
15 g oral glucose (CHO) from dextrose tablets (Dextro Energy GmbH & Co. KG, Germany)	
Reporting group title	80 µg s.c. dasiglucagon (D80)
Reporting group description:	
80 µg dasiglucagon (D80) s.c. injection into a lifted skinfold of the abdominal wall.	
Reporting group title	120 µg dasiglucagon (D120)
Reporting group description:	
120 µg dasiglucagon (D120) s.c. injection into a lifted skinfold of the abdominal wall.	
Subject analysis set title	15 g oral glucose (CHO)
Subject analysis set type	Full analysis
Subject analysis set description:	
15 g oral glucose (CHO) intervention	
Subject analysis set title	80 µg s.c. dasiglucagon (D80)
Subject analysis set type	Full analysis
Subject analysis set description:	
80 µg s.c. dasiglucagon (D80) intervention	
Subject analysis set title	120 µg s.c. dasiglucagon (D120)
Subject analysis set type	Full analysis
Subject analysis set description:	
120 µg s.c. dasiglucagon (D120) intervention	

Primary: Time below target glucose range (<3.9 mmol/L)

End point title	Time below target glucose range (<3.9 mmol/L)[1]
End point description:	
End point type	Primary
End point timeframe:	
From intervention (t=0) until the end of the observation period (t=180 min)	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: In cases where oral rescue treatment was provided, the nadir plasma glucose concentration was carried forward to the end of the observation period (t=180) in data analysis. Missing plasma glucose values were extrapolated from the closest measurements using linear interpolation. The three-way comparison of the interventions were compared using a repeated-measures ANOVA analysis (p=0.273).

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: percent				
arithmetic mean (standard error)	14 (± 6)	7 (± 3)	6 (± 3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Hypoglycemia events (<3.9 mmol/L)

End point title	Hypoglycemia events (<3.9 mmol/L)

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: No. of subjects	10	5	4	

Statistical analyses

No statistical analyses for this end point

Secondary: Oral glucose rescue treatment events (<3.0 mmol/L)

End point title	Oral glucose rescue treatment events (<3.0 mmol/L)

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: No. of subjects	4	3	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to oral glucose rescue treatment

End point title	Time to oral glucose rescue treatment

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: minute				
arithmetic mean (standard error)	120 (± 30)	160 (± 3)	110 (± 10)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to glucose increase of 1.1 mmol/L

End point title	Time to glucose increase of 1.1 mmol/L

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: minute				
median (standard error)	30 (± 3.5)	15 (± 1.6)	15 (± 1.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time in target glucose range (3.9-10.0 mmol/L)

End point title	Time in target glucose range (3.9-10.0 mmol/L)

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: percent				
arithmetic mean (standard error)	85 (± 6)	92 (± 3)	88 (± 5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time above target glucose range (>10.0 mmol/L)

End point title	Time above target glucose range (>10.0 mmol/L)

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: percent				
arithmetic mean (standard error)	1 (± 1)	1 (± 1)	5 (± 4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Hyperglycemia events (>10.0 mmol/L)

End point title	Hyperglycemia events (>10.0 mmol/L)

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: No. of subjects	1	1	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Peak glucose

End point title	Peak glucose

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: mmol/L				
arithmetic mean (standard error)	7.5 (± 0.3)	7.7 (± 0.3)	8.4 (± 0.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Incremental peak glucose

End point title	Incremental peak glucose

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: mmol/L				
arithmetic mean (standard error)	3 (± 0.3)	3.1 (± 0.3)	3.8 (± 0.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean glucose

End point title	Mean glucose

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: mmol/L				
arithmetic mean (standard error)	5.6 (± 0.3)	6.3 (± 0.3)	6.7 (± 0.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Nadir glucose

End point title	Nadir glucose

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: mmol/L				
median (standard error)	3.9 (± 0.1)	4.5 (± 0.2)	4.5 (± 0.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to peak glucose

End point title	Time to peak glucose

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: minute				
arithmetic mean (standard error)	56 (± 3.7)	53 (± 3)	55 (± 3.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Glucose total Area Under the Curve

End point title	Glucose total Area Under the Curve

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: mmol/L/min(t0-t180)				
arithmetic mean (standard error)	1004 (± 49)	1123 (± 52)	1216 (± 63)	

Statistical analyses

No statistical analyses for this end point

Secondary: Baseline serum insulin

End point title	Baseline serum insulin

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: pmol/L				
arithmetic mean (standard error)	60 (± 11)	64 (± 13)	72 (± 12)	

Statistical analyses

No statistical analyses for this end point

Secondary: Insulin bolus at baseline

End point title	Insulin bolus at baseline

End point description:

End point type	Secondary

End point timeframe:

At baseline

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: units				
arithmetic mean (standard error)	3 (± 0.4)	2.7 (± 0.3)	2.8 (± 0.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Serum insulin at time of intervention

End point title	Serum insulin at time of intervention

End point description:

End point type	Secondary

End point timeframe:

At the time of intervention (t=0)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: pmol/L				
arithmetic mean (standard error)	130 (± 24)	117 (± 21)	112 (± 14)	

Statistical analyses

No statistical analyses for this end point

Secondary: Serum insulin total Area Under the Curve

End point title	Serum insulin total Area Under the Curve

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	15 g oral glucose (CHO)	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	19	20	
Units: pmol/L/min(t0-t180)				
arithmetic mean (standard error)	17159 (± 2598)	16929 (± 3092)	16177 (± 2164)	

Statistical analyses

No statistical analyses for this end point

Secondary: Peak plasma dasiglucagon

End point title	Peak plasma dasiglucagon

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	19	20		
Units: pmol/L				
arithmetic mean (standard error)	283 (± 29)	409 (± 43)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to peak plasma dasiglucagon

End point title	Time to peak plasma dasiglucagon

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	19	20		
Units: minute				
arithmetic mean (standard error)	24 (± 1.6)	23 (± 1.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma dasiglucagon total Area Under the Curve

End point title	Plasma dasiglucagon total Area Under the Curve

End point description:

End point type	Secondary

End point timeframe:

From intervention (t=0) until the end of the observation period (t=180 min)

End point values	80 µg s.c. dasiglucagon (D80)	120 µg s.c. dasiglucagon (D120)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	19	20		
Units: pmol/L/min(t0-t180)				
arithmetic mean (standard error)	17592 (± 872)	26918 (± 1591)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From intervention (t=0) to the end of the observation period (t=180 min)

Adverse event reporting additional description:

Adverse effects (nausea, headache, stomachache, palpitations and injection site pain) were scored using a 0-100 visual analog scale (VAS) just prior to the intervention (t=0) and three hours later (t=180) to evaluate whether any adverse events had occurred within three hours after the intervention.

Assessment type	Systematic

Dictionary used

Dictionary name	None
Dictionary version	0

Reporting groups

Reporting group title	15 g oral glucose (CHO)

Reporting group description:

Subjects who received 15 g oral glucose

Reporting group title	80 ug dasiglucagon (D80)

Reporting group description:

Subjects who received 80 ug dasiglucagon

Reporting group title	120 ug dasiglucagon (D120)

Reporting group description:

Subjects who received 120 ug dasiglucagon

Serious adverse events	15 g oral glucose (CHO)	80 ug dasiglucagon (D80)	120 ug dasiglucagon (D120)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 19 (0.00%)	0 / 20 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	15 g oral glucose (CHO)	80 ug dasiglucagon (D80)	120 ug dasiglucagon (D120)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 20 (25.00%)	8 / 19 (42.11%)	8 / 20 (40.00%)
General disorders and administration site conditions			
Nausea	Additional description: If scoring of nausea (using a visual analog scale) was higher after exposure to the intervention (up to 3 hours after) compared to baseline (t = 0).		
subjects affected / exposed	1 / 20 (5.00%)	5 / 19 (26.32%)	5 / 20 (25.00%)
occurrences (all)	1	5	5

Headache	Additional description: If scoring of headache (using a visual analog scale) was higher after exposure to the intervention (up to 3 hours after) compared to baseline (t = 0).		
subjects affected / exposed	4 / 20 (20.00%)	5 / 19 (26.32%)	4 / 20 (20.00%)
occurrences (all)	4	5	4
Stomachache	Additional description: If scoring of stomachache (using a visual analog scale) was higher after exposure to the intervention (up to 3 hours after) compared to baseline (t = 0).		
subjects affected / exposed	0 / 20 (0.00%)	2 / 19 (10.53%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Palpitations	Additional description: If scoring of (subjective feeling of) palpitations (using a visual analog scale) was higher after exposure to the intervention (up to 3 hours after) compared to baseline (t = 0).		
subjects affected / exposed	2 / 20 (10.00%)	3 / 19 (15.79%)	1 / 20 (5.00%)
occurrences (all)	2	3	1
Injection site pain	Additional description: If injection site pain was noticed after exposure to the intervention (up to 3 hours after).		
subjects affected / exposed	0 / 20 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported