Clinical trial results:
Effect and safety of semaglutide 7.2 mg once-weekly in participants with obesity

Summary

EudraCT number	2022-000790-94
Trial protocol	GR PT NO SK HU BG
Global end of trial date	26 November 2024

Results information

Result version number	v1 (current)
This version publication date	12 December 2025
First version publication date	12 December 2025

Trial information

Trial identification

Sponsor protocol code	NN9536-4999

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05646706
WHO universal trial number (UTN)	U1111-1274-4259

Notes:

Sponsors

Sponsor organisation name	Novo Nordisk A/S
Sponsor organisation address	Novo Alle, Bagsvaerd, Denmark, 2880
Public contact	Clinical Reporting Office (2834), Novo Nordisk A/S, clinicaltrials@novonordisk.com
Scientific contact	Clinical Reporting Office (2834), Novo Nordisk A/S, clinicaltrials@novonordisk.com

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	10 March 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 November 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

-To demonstrate the superiority of semaglutide subcutaneous (s.c.) 7.2 milligrams (mg) once weekly versus placebo as an adjunct to a reduced calorie diet and increased physical activity, with respect to relative change and achieving greater than or equal to (>=) 5 percentage (%) reduction in body weight after 72 weeks, in adults with obesity.

Protection of trial subjects:

This study was conducted in accordance with the International Council for Harmonization (ICH) Good Clinical Practice (GCP), the Declaration of Helsinki, and Food and Drug Administration (FDA) 21 Code of Federal Regulations (CFR) 312.120. Essential documents will be maintained and archived in accordance with ICH GCP.

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	04 January 2023
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	Bulgaria: 118
Country: Number of subjects enrolled	Canada: 68
Country: Number of subjects enrolled	Germany: 139
Country: Number of subjects enrolled	Greece: 173
Country: Number of subjects enrolled	Hungary: 93
Country: Number of subjects enrolled	Norway: 50
Country: Number of subjects enrolled	Poland: 122
Country: Number of subjects enrolled	Portugal: 34
Country: Number of subjects enrolled	Slovakia: 100
Country: Number of subjects enrolled	United States: 404
Country: Number of subjects enrolled	South Africa: 106
Worldwide total number of subjects	1407
EEA total number of subjects	829

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)	1309
From 65 to 84 years	98
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The trial was conducted at 90 sites in 11 countries as follows: Bulgaria, Canada, Germany, Greece, Hungary, Norway, Poland, Portugal, Slovakia, South Africa, and the Unites States.

Pre-assignment

Screening details:

The trial included a treatment period of 72 weeks (20 weeks of dose escalation and 52 weeks of maintenance period) followed by 9-week follow-up period. Subjects were randomized in 5:1:1 ratio in either semaglutide 7.2 mg, semaglutide 2.4 mg or placebo as an adjunct to reduced-calorie diet and increased physical activity.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Semaglutide 7.2 mg

Arm description:

Subjects received Semaglutide subcutaneously once weekly in a fixed-dose escalation manner, with dose increases every 4 weeks for up to week 20 (0.25 mg, 0.5 mg, 1.0 mg, 1.7 mg, 2.4 mg) followed by maintenance dose of 7.2 mg once weekly up to week 72.

Arm type	Experimental
Investigational medicinal product name	Semaglutide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received Semaglutide injection once weekly at the same day of the week. Injections were to be administered in the thigh, abdomen or upper arm at any time of day irrespective of meals.

Arm title	Semaglutide 2.4 mg

Arm description:

Subjects received Semaglutide subcutaneously once weekly in a fixed-dose escalation manner, with dose increases every 4 weeks for up to week 20 (0.25 mg, 0.5 mg, 1.0 mg, 1.7 mg, 2.4 mg) followed by maintenance dose of 2.4 mg once weekly up to week 72.

Arm type	Experimental
Investigational medicinal product name	Semaglutide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received Semaglutide injection once weekly at the same day of the week. Injections were to be administered in the thigh, abdomen or upper arm at any time of day irrespective of meals.

Arm title	Placebo

Arm description:

Subjects received placebo (matched to Semaglutide) subcutaneously once weekly for up to week 72.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received placebo (matched to Semaglutide) injection once weekly at the same day of the week. Injections were to be administered in the thigh, abdomen or upper arm at any time of day irrespective of meals.

Number of subjects in period 1	Semaglutide 7.2 mg	Semaglutide 2.4 mg	Placebo
Started	1005	201	201
Full analysis set	1005	201	201
Safety analysis set	1004	201	201
Completed	959	190	180
Not completed	46	11	21
Consent withdrawn by subject	18	6	16
Physician decision	4	-	-
Lost to follow-up	24	5	5

Baseline characteristics

Reporting groups	
Reporting group title	Semaglutide 7.2 mg
Reporting group description:	
Subjects received Semaglutide subcutaneously once weekly in a fixed-dose escalation manner, with dose increases every 4 weeks for up to week 20 (0.25 mg, 0.5 mg, 1.0 mg, 1.7 mg, 2.4 mg) followed by maintenance dose of 7.2 mg once weekly up to week 72.	
Reporting group title	Semaglutide 2.4 mg
Reporting group description:	
Subjects received Semaglutide subcutaneously once weekly in a fixed-dose escalation manner, with dose increases every 4 weeks for up to week 20 (0.25 mg, 0.5 mg, 1.0 mg, 1.7 mg, 2.4 mg) followed by maintenance dose of 2.4 mg once weekly up to week 72.	
Reporting group title	Placebo
Reporting group description:	
Subjects received placebo (matched to Semaglutide) subcutaneously once weekly for up to week 72.	

Reporting group values	Semaglutide 7.2 mg	Semaglutide 2.4 mg	Placebo
Number of subjects	1005	201	201
Age Categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	47	46	48
standard deviation	± 12	± 12	± 12
Gender Categorical Units: Subjects			
Female	753	137	147
Male	252	64	54

Reporting group values	Total		
Number of subjects	1407		
Age Categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender Categorical Units: Subjects			
Female	1037		
Male	370		

Subject analysis sets	
Subject analysis set title	Pooled Semaglutide (7.2 mg + 2.4 mg)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received semaglutide subcutaneously once weekly in a fixed-dose escalation manner, with dose increases every 4 weeks for up to week 20 (0.25 mg, 0.5 mg, 1.0 mg, 1.7 mg, 2.4 mg) followed by maintenance dose of either 7.2 mg or 2.4 mg once weekly up to week 72. Pooled Semaglutide group was used as sub-population for MRI assessment.

Reporting group values	Pooled Semaglutide (7.2 mg + 2.4 mg)		
Number of subjects	49		
Age Categorical Units: Subjects			

Age Continuous Units: years			
arithmetic mean	0		
standard deviation	± 0		
Gender Categorical Units: Subjects			
Female	39		
Male	10		

End points

End points reporting groups

Reporting group title	Semaglutide 7.2 mg

Reporting group description:

Subjects received Semaglutide subcutaneously once weekly in a fixed-dose escalation manner, with dose increases every 4 weeks for up to week 20 (0.25 mg, 0.5 mg, 1.0 mg, 1.7 mg, 2.4 mg) followed by maintenance dose of 7.2 mg once weekly up to week 72.

Reporting group title	Semaglutide 2.4 mg

Reporting group description:

Subjects received Semaglutide subcutaneously once weekly in a fixed-dose escalation manner, with dose increases every 4 weeks for up to week 20 (0.25 mg, 0.5 mg, 1.0 mg, 1.7 mg, 2.4 mg) followed by maintenance dose of 2.4 mg once weekly up to week 72.

Reporting group title	Placebo

Reporting group description:

Subjects received placebo (matched to Semaglutide) subcutaneously once weekly for up to week 72.

Subject analysis set title	Pooled Semaglutide (7.2 mg + 2.4 mg)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received semaglutide subcutaneously once weekly in a fixed-dose escalation manner, with dose increases every 4 weeks for up to week 20 (0.25 mg, 0.5 mg, 1.0 mg, 1.7 mg, 2.4 mg) followed by maintenance dose of either 7.2 mg or 2.4 mg once weekly up to week 72. Pooled Semaglutide group was used as sub-population for MRI assessment.

Primary: Semaglutide 7.2 mg versus Placebo: Relative change in body weight

End point title	Semaglutide 7.2 mg versus Placebo: Relative change in body weight[1]

End point description:

Relative change in body weight from baseline (week 0) to end of treatment (week 72) is presented. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Primary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	950	171		
Units: Percentage (%) of body weight				
arithmetic mean (standard deviation)	-19.5 (± 10.6)	-3.8 (± 7.1)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Week 72 responses were analysed using an analysis of covariance model with randomised treatment as

factor and baseline body weight as covariate.

Comparison groups	Semaglutide 7.2 mg v Placebo
Number of subjects included in analysis	1121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Treatment difference
Point estimate	-14.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.21
upper limit	-13.41

Primary: ≥5% body weight reduction (yes/no)

End point title	≥5% body weight reduction (yes/no)[2]

End point description:

Number of subjects who achieve body weight reduction >=5% from baseline (week 0) is presented in categories as "yes" or "no" where "yes" defines subjects who achieved body weight reduction >=5% and "no" defines subjects who did not achieve body weight reduction >=5%. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Primary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	950	171		
Units: Subjects				
Yes	862	63		
No	88	108		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Week 72 responses were analysed using a binary regression model with randomized treatment as factor and baseline value as covariate.

Comparison groups	Semaglutide 7.2 mg v Placebo

Number of subjects included in analysis	1121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Binary regression model
Parameter estimate	Odds ratio (OR)
Point estimate	12.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.32
upper limit	17.61

Secondary: ≥10% body weight reduction (yes/no)

End point title	≥10% body weight reduction (yes/no)[3]

End point description:

Number of subjects who achieve body weight reduction >=10% from baseline (week 0) is presented in categories as "yes" or "no" where "yes" defines subjects who achieved body weight reduction >=10% and "no" defines subjects who did not achieve body weight reduction >=10%. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	950	171		
Units: Subjects				
Yes	783	35		
No	167	136		

Statistical analyses

No statistical analyses for this end point

Secondary: ≥15% body weight reduction (yes/no)

End point title	≥15% body weight reduction (yes/no)[4]

End point description:

Number of subjects who achieve body weight reduction >=15% from baseline (week 0) is presented in categories as "yes" or "no" where "yes" defines subjects who achieved body weight reduction >=15% and "no" defines subjects who did not achieve body weight reduction >=15%. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be

assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	950	171		
Units: Subjects				
Yes	632	13		
No	318	158		

Statistical analyses

No statistical analyses for this end point

Secondary: ≥20% body weight reduction (yes/no)

End point title	≥20% body weight reduction (yes/no)

End point description:

Number of subjects who achieve body weight reduction >=20% from baseline (week 0) is presented in categories as "yes" or "no" where "yes" defines subjects who achieved body weight reduction >=20% and "no" defines subjects who did not achieve body weight reduction >=20%. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

End point values	Semaglutide 7.2 mg	Semaglutide 2.4 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	950	189	171	
Units: Subjects				
Yes	453	63	5	
No	497	126	166	

Statistical analyses

No statistical analyses for this end point

Secondary: ≥25% body weight reduction (yes/no)

End point title	≥25% body weight reduction (yes/no)

End point description:

Number of subjects who achieve body weight reduction >=25% from baseline (week 0) is presented in categories as "yes" or "no" where "yes" defines subjects who achieved body weight reduction >=25% and "no" defines subjects who did not achieve body weight reduction >=25%. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

End point values	Semaglutide 7.2 mg	Semaglutide 2.4 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	950	189	171	
Units: Subjects				
Yes	296	29	0	
No	654	160	171	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in waist circumference

End point title	Change in waist circumference[5]

End point description:

Change in waist circumference from baseline (week 0) to end of treatment (week 72) is presented. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	950	171		
Units: Centimeter (cm)				
arithmetic mean (standard deviation)	-18.0 (± 10.5)	-5.6 (± 7.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Semaglutide 7.2 mg versus Semaglutide 2.4 mg: Relative change in body weight

End point title	Semaglutide 7.2 mg versus Semaglutide 2.4 mg: Relative change in body weight[6]

End point description:

Relative change in body weight from baseline (week 0) to end of treatment (week 72) is presented. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and semaglutide 2.4 mg groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and semaglutide 2.4 mg groups.

End point values	Semaglutide 7.2 mg	Semaglutide 2.4 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	950	189		
Units: % of body weight				
arithmetic mean (standard deviation)	-19.5 (± 10.6)	-16.4 (± 9.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in body weight

End point title	Change in body weight

End point description:

Change in body weight from baseline (week 0) to end of treatment (week 72) is presented. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

End point values	Semaglutide 7.2 mg	Semaglutide 2.4 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	950	189	171	
Units: Kilograms (kg)				
arithmetic mean (standard deviation)	-21.7 (± 12.3)	-18.7 (± 10.4)	-4.3 (± 8.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in body mass index (BMI)

End point title	Change in body mass index (BMI)[7]

End point description:

Change in BMI from baseline (week 0) to end of treatment (week 72) is presented. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	950	171		
Units: kilogram per square meter (kg/m^2)				
arithmetic mean (standard deviation)	-7.7 (± 4.4)	-1.5 (± 2.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in total fat mass (%)

End point title	Change in total fat mass (%)[8]

End point description:

Change in total fat mass (%) from baseline (week 0) to end of treatment (week 72) is presented. MRI analysis set included all subjects in the sub-population of Full analysis set that have had a valid MRI scan performed at baseline. Number of subjects analyzed = Subjects with available data for the endpoint. As defined in Statistical Analysis Plan (SAP) section 4.3.2, the reporting groups semaglutide 7.2 and semaglutide 2.4 mg were planned to be pooled for analysis of the endpoint. Hence, data is represented in singled pooled semaglutide (7.2mg + 2.4mg) arm.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for single pooled semaglutide (7.2 mg + 2.4 mg) and placebo groups.

End point values	Placebo	Pooled Semaglutide (7.2 mg + 2.4 mg)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	5	45		
Units: % of total fat mass				
arithmetic mean (standard deviation)	-2.7 (± 7.3)	-26.9 (± 18.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in total fat mass (liters)

End point title	Change in total fat mass (liters)[9]

End point description:

Change in total fat mass (liters) from baseline (week 0) to end of treatment (week 72) is presented. MRI analysis set included all subjects in the sub-population of Full analysis set that have had a valid MRI scan performed at baseline. Number of subjects analyzed = Subjects with available data for the endpoint. As defined in SAP section 4.3.2, the reporting groups semaglutide 7.2 mg and semaglutide 2.4 mg were planned to be pooled for analysis of the endpoint. Hence, data is represented in singled pooled semaglutide (7.2 mg + 2.4 mg) arm.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for single pooled semaglutide (7.2 mg + 2.4 mg) and placebo groups.

End point values	Placebo	Pooled Semaglutide (7.2 mg + 2.4 mg)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	5	45		
Units: liters				
arithmetic mean (standard deviation)	-1.5 (± 4.1)	-11.7 (± 8.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in lean body mass (%)

End point title	Change in lean body mass (%)[10]

End point description:

Change in lean body mass (%) from baseline (week 0) to end of treatment (week 72) is presented. MRI analysis set included all subjects in the sub-population of Full analysis set that have had a valid MRI scan performed at baseline. Number of subjects analyzed = Subjects with available data for the endpoint. As defined in SAP section 4.3.2, the reporting groups semaglutide 7.2 mg and semaglutide 2.4 mg were planned to be pooled for analysis of the endpoint. Hence, data is represented in singled pooled semaglutide (7.2 mg + 2.4 mg) arm.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for single pooled semaglutide (7.2 mg + 2.4 mg) and placebo groups.

End point values	Placebo	Pooled Semaglutide (7.2 mg + 2.4 mg)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	5	45		
Units: % of lean body mass				
arithmetic mean (standard deviation)	-0.4 (± 4.2)	-7.5 (± 7.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in lean body mass (liters)

End point title	Change in lean body mass (liters)[11]

End point description:

Change in lean body mass (liters) from baseline (week 0) to end of treatment (week 72) is presented. MRI analysis set included all subjects in the sub-population of Full analysis set that have had a valid MRI scan performed at baseline. Number of subjects analyzed = Subjects with available data for the endpoint. As defined in SAP section 4.3.2, the reporting groups semaglutide 7.2 mg and semaglutide 2.4 mg were planned to be pooled for analysis of the endpoint. Hence, data is represented in singled pooled semaglutide (7.2 mg + 2.4 mg) arm.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for single pooled semaglutide (7.2 mg + 2.4 mg) and placebo groups.

End point values	Placebo	Pooled Semaglutide (7.2 mg + 2.4 mg)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	5	45		
Units: liters				
arithmetic mean (standard deviation)	-0.2 (± 0.9)	-1.9 (± 2.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in visceral fat mass (%)

End point title	Change in visceral fat mass (%)[12]

End point description:

Change in visceral fat mass (%) from baseline (week 0) to end of treatment (week 72) is presented. MRI analysis set included all subjects in the sub-population of Full analysis set that have had a valid MRI scan performed at baseline. Number of subjects analyzed = Subjects with available data for the endpoint. As defined in SAP section 4.3.2, the reporting groups semaglutide 7.2 mg and semaglutide 2.4 mg were planned to be pooled for analysis of the endpoint. Hence, data is represented in singled pooled semaglutide (7.2 mg + 2.4 mg) arm.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for single pooled semaglutide (7.2 mg + 2.4 mg) and placebo groups.

End point values	Placebo	Pooled Semaglutide (7.2 mg + 2.4 mg)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	5	45		
Units: % of visceral fat mass				
arithmetic mean (standard deviation)	-8.8 (± 16.0)	-33.6 (± 22.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in visceral fat mass (liters)

End point title	Change in visceral fat mass (liters)[13]

End point description:

Change in visceral fat mass (liters) from baseline (week 0) to end of treatment (week 72) is presented. MRI analysis set included all subjects in the sub-population of Full analysis set that have had a valid MRI scan performed at baseline. Number of subjects analyzed = Subjects with available data for the endpoint. As defined in SAP section 4.3.2, the reporting groups semaglutide 7.2 mg and semaglutide 2.4

mg were planned to be pooled for analysis of the endpoint. Hence, data is represented in singled pooled semaglutide (7.2 mg + 2.4 mg) arm.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for single pooled semaglutide (7.2 mg + 2.4 mg) and placebo groups.

End point values	Placebo	Pooled Semaglutide (7.2 mg + 2.4 mg)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	5	45		
Units: liters				
arithmetic mean (standard deviation)	-0.2 (± 0.6)	-1.8 (± 1.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in systolic blood pressure

End point title	Change in systolic blood pressure[14]

End point description:

Change in systolic blood pressure from baseline (week 0) to end of treatment (week 72) is presented. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	949	171		
Units: millimeters of mercury (mmHg)				
arithmetic mean (standard deviation)	-10 (± 14)	-4 (± 12)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in diastolic blood pressure

End point title	Change in diastolic blood pressure[15]

End point description:

Change in diastolic blood pressure from baseline (week 0) to end of treatment (week 72) is presented. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	949	171		
Units: mmHg				
arithmetic mean (standard deviation)	-5 (± 9)	-1 (± 9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in total cholesterol (milligram per deciliter [mg/dL]) - Ratio to Baseline

End point title	Change in total cholesterol (milligram per deciliter [mg/dL]) - Ratio to Baseline[16]

End point description:

Change in total cholesterol in mg/dL from baseline (week 0) to end of treatment (week 72) is presented as ratio to baseline (week 0). Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	935	167		
Units: Ratio of total cholesterol				
geometric mean (geometric coefficient of variation)	0.94 (± 16.7)	1.00 (± 16.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in total cholesterol (millimoles per liter [mmol/L]) - Ratio to Baseline

End point title	Change in total cholesterol (millimoles per liter [mmol/L]) - Ratio to Baseline[17]

End point description:

Change in total cholesterol in mmol/L from baseline (week 0) to end of treatment (week 72) is presented as ratio to baseline (week 0). Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	935	167		
Units: Ratio of total cholesterol				
geometric mean (geometric coefficient of variation)	0.94 (± 16.7)	1.00 (± 16.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in high-density lipoprotein (HDL) cholesterol (mg/dL) - Ratio to Baseline

End point title	Change in high-density lipoprotein (HDL) cholesterol (mg/dL) - Ratio to Baseline[18]

End point description:

Change in HDL cholesterol in mg/dL from baseline (week 0) to end of treatment (week 72) is presented as ratio to baseline (week 0). Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	921	165		
Units: Ratio of HDL cholesterol				
geometric mean (geometric coefficient of variation)	1.08 (± 15.9)	1.02 (± 15.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in high-density lipoprotein (HDL) cholesterol (mmol/L) - Ratio to Baseline

End point title	Change in high-density lipoprotein (HDL) cholesterol (mmol/L) - Ratio to Baseline[19]

End point description:

Change in HDL cholesterol in mmol/L from baseline (week 0) to end of treatment (week 72) is presented as ratio to baseline (week 0). Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	921	165		
Units: Ratio of HDL cholesterol				
geometric mean (geometric coefficient of variation)	1.08 (± 15.9)	1.02 (± 15.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in low-density lipoprotein (LDL) cholesterol (mg/dL) - Ratio to Baseline

End point title	Change in low-density lipoprotein (LDL) cholesterol (mg/dL) - Ratio to Baseline[20]

End point description:

Change in LDL cholesterol in mg/dL from baseline (week 0) to end of treatment (week 72) is presented as ratio to baseline (week 0). Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	921	165		
Units: Ratio of LDL cholesterol				
geometric mean (geometric coefficient of variation)	0.92 (± 25.5)	0.98 (± 28.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in low-density lipoprotein (LDL) cholesterol (mmol/L) - Ratio to Baseline

End point title	Change in low-density lipoprotein (LDL) cholesterol (mmol/L) - Ratio to Baseline[21]

End point description:

Change in LDL cholesterol in mmol/L from baseline (week 0) to end of treatment (week 72) is presented as ratio to baseline (week 0). Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	921	165		
Units: Ratio of LDL cholesterol				
geometric mean (geometric coefficient of variation)	0.92 (± 25.5)	0.98 (± 28.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in very low-density lipoprotein (VLDL) cholesterol (mg/dL) - Ratio to Baseline

End point title	Change in very low-density lipoprotein (VLDL) cholesterol (mg/dL) - Ratio to Baseline[22]

End point description:

Change in VLDL cholesterol in mg/dL from baseline (week 0) to end of treatment (week 72) is presented as ratio to baseline (week 0). Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	931	165		
Units: Ratio of VLDL cholesterol				
geometric mean (geometric coefficient of variation)	0.76 (± 39.3)	1.00 (± 36.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in very low-density lipoprotein (VLDL) cholesterol (mmol/L) - Ratio to Baseline

End point title	Change in very low-density lipoprotein (VLDL) cholesterol (mmol/L) - Ratio to Baseline[23]

End point description:

Change in VLDL cholesterol in mmol/L from baseline (week 0) to end of treatment (week 72) is presented as ratio to baseline (week 0). Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	931	165		
Units: Ratio of VLDL cholesterol				
geometric mean (geometric coefficient of variation)	0.76 (± 39.3)	1.00 (± 36.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in triglycerides (mg/dL) - Ratio to Baseline

End point title	Change in triglycerides (mg/dL) - Ratio to Baseline[24]

End point description:

Change in triglycerides in mg/dL from baseline (week 0) to end of treatment (week 72) is presented as ratio to baseline (week 0). Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	933	165		
Units: Ratio of triglycerides				
geometric mean (geometric coefficient of variation)	0.76 (± 40.9)	0.99 (± 38.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in triglycerides (mmol/L) - Ratio to Baseline

End point title	Change in triglycerides (mmol/L) - Ratio to Baseline[25]

End point description:

Change in triglycerides in mmol/L from baseline (week 0) to end of treatment (week 72) is presented as ratio to baseline (week 0). Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	933	165		
Units: Ratio of triglycerides				
geometric mean (geometric coefficient of variation)	0.76 (± 40.9)	0.99 (± 38.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in high-sensitivity c-reactive protein (hsCRP) - Ratio to Baseline

End point title	Change in high-sensitivity c-reactive protein (hsCRP) - Ratio to Baseline[26]

End point description:

Change in hsCRP (milligram per liter [mg/L]) from baseline (week 0) to end of treatment (week 72) is presented as ratio to baseline (week 0). Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	934	167		
Units: Ratio of hsCRP				
geometric mean (geometric coefficient of variation)	0.38 (± 128.9)	0.89 (± 89.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in lipid-lowering treatment (decrease, no change, increase)

End point title	Change in lipid-lowering treatment (decrease, no change, increase)[27]

End point description:

Number of subjects with change in lipid-lowering treatment from baseline (week 0) is presented in categories as decrease, no change and increase. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	163	28		
Units: Subjects				
Decreased	8	0		
No change	138	22		
Increased	17	6		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in antihypertensive treatment (decrease, no change, increase)

End point title	Change in antihypertensive treatment (decrease, no change, increase)[28]

End point description:

Number of subjects with change in antihypertensive treatment from baseline (week 0) is presented in categories as decrease, no change and increase. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	322	59		
Units: Subjects				
Decreased	57	6		
No change	233	47		
Increased	32	6		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in glycated haemoglobin (HbA1c)

End point title	Change in glycated haemoglobin (HbA1c)[29]

End point description:

Change in HbA1c from baseline (week 0) to end of treatment (week 72) is presented. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	938	167		
Units: % of HbA1c				
arithmetic mean (standard deviation)	-0.3 (± 0.3)	0.0 (± 0.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in fasting plasma glucose

End point title	Change in fasting plasma glucose[30]

End point description:

Change in fasting plasma glucose from baseline (week 0) to end of treatment (week 72) is presented. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	923	160		
Units: mg/dL				
arithmetic mean (standard deviation)	-11.7 (± 11.9)	-1.7 (± 11.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in fasting serum insulin (picomoles per liter [pmol/L]) - Ratio to Baseline

End point title	Change in fasting serum insulin (picomoles per liter [pmol/L]) - Ratio to Baseline[31]

End point description:

Change in fasting serum insulin in pmol/L from baseline (week 0) to end of treatment (week 72) is presented as ratio to baseline (week 0). Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[31] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	902	158		
Units: Ratio of fasting serum insulin				
geometric mean (geometric coefficient of variation)	0.61 (± 66.6)	0.90 (± 62.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in fasting serum insulin (milliinternational units per milliliter [mIU/mL]) - Ratio to Baseline

End point title	Change in fasting serum insulin (milliinternational units per milliliter [mIU/mL]) - Ratio to Baseline[32]

End point description:

Change in fasting serum insulin in mIU/ml from baseline (week 0) to end of treatment (week 72) is presented as ratio to baseline (week 0). Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	902	158		
Units: Ratio of fasting serum insulin				
geometric mean (geometric coefficient of variation)	0.61 (± 66.6)	0.90 (± 62.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in glycaemic category (Normo-glycaemia, pre-diabetes, type 2 diabetes [T2D])

End point title	Change in glycaemic category (Normo-glycaemia, pre-diabetes, type 2 diabetes [T2D])[33]

End point description:

Number of subjects with change in glycaemic categories from baseline (week 0) presented as Normo-glycaemia, pre-diabetes, type 2 diabetes. Full analysis set included all randomized subjects. Subjects were analysed according to the randomised treatment. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[33] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	951	168		
Units: Subjects				
Normo-glycaemia to Normo-glycaemia	574	75		
Normo-glycaemia to Pre-diabetes	21	20		
Normo-glycaemia to Diabetes	0	2		
Pre-diabetes to Normo-glycaemia	297	26		
Pre-diabetes to Pre-diabetes	59	42		
Pre-diabetes to Diabetes	0	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of adverse events (AEs)

End point title	Number of adverse events (AEs)

End point description:

Number of AEs is reported. An AE is any untoward medical occurrence in a clinical study subjects that is temporally associated with the use of investigational medicinal product (IMP), whether or not considered related to the IMP. Safety analysis set included all subjects who were exposed to at least one dose of randomised trial product. Subjects were analysed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of study (week 81)

End point values	Semaglutide 7.2 mg	Semaglutide 2.4 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1004	201	201	
Units: Events	6430	1133	743	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of serious adverse events (SAEs)

End point title	Number of serious adverse events (SAEs)

End point description:

Number of SAEs is reported. A SAE is any untoward medical occurrence that fulfils at least one of the following criteria: results in death, is life threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect or important medical event. Safety analysis set included all subjects who were exposed to at least one dose of randomised trial product. Subjects were analysed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of study (week 81)

End point values	Semaglutide 7.2 mg	Semaglutide 2.4 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1004	201	201	
Units: Events	100	31	16	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in pulse

End point title	Change in pulse[34]

End point description:

Change in pulse from baseline (week 0) to end of treatment (week 72) is presented. Safety analysis set included all subjects who were exposed to at least one dose of randomised trial product. Subjects were analysed according to the treatment they actually received. Number of subjects analyzed = Subjects with available data for the endpoint. The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point type	Secondary

End point timeframe:

From baseline (week 0) to end of treatment (week 72)

Notes:

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for semaglutide 7.2 mg and placebo groups.

End point values	Semaglutide 7.2 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	872	140		
Units: Beats per minute (bpm)				
arithmetic mean (standard deviation)	1 (± 10)	-2 (± 11)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From baseline (week 0) to end of study (week 81)

Adverse event reporting additional description:

Safety analysis set included all subjects who were exposed to at least one dose of randomised trial product. Adverse events were assessment based on safety analysis set and all cause mortality was assessed for all randomized subjects in this study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22

Reporting groups

Reporting group title	Semaglutide 7.2 mg

Reporting group description:

Subjects received Semaglutide subcutaneously once weekly in a fixed-dose escalation manner, with dose increases every 4 weeks for up to week 20 (0.25 mg, 0.5 mg, 1.0 mg, 1.7 mg, 2.4 mg) followed by maintenance dose of 7.2 mg once weekly up to week 72.

Reporting group title	Placebo

Reporting group description:

Subjects received placebo (matched to Semaglutide) subcutaneously once weekly for up to week 72.

Reporting group title	Semaglutide 2.4 mg

Reporting group description:

Subjects received Semaglutide subcutaneously once weekly in a fixed-dose escalation manner, with dose increases every 4 weeks for up to week 20 (0.25 mg, 0.5 mg, 1.0 mg, 1.7 mg, 2.4 mg) followed by maintenance dose of 2.4 mg once weekly up to week 72.

Serious adverse events	Semaglutide 7.2 mg	Placebo	Semaglutide 2.4 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	73 / 1004 (7.27%)	11 / 201 (5.47%)	22 / 201 (10.95%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adrenal adenoma			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast angiosarcoma			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			

subjects affected / exposed	2 / 1004 (0.20%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroadenoma of breast			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal papilloma of breast			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 1004 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroma			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parathyroid tumour benign			

subjects affected / exposed	0 / 1004 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testis cancer			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 1004 (0.10%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion threatened			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General disorders and administration site conditions			
Capsular contracture associated with breast implant			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Adenomyosis			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Menometrorrhagia			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	2 / 1004 (0.20%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			

subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	2 / 1004 (0.20%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	2 / 1004 (0.20%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			

subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Liver function test increased			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ulna fracture			
subjects affected / exposed	0 / 1004 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure chronic			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			

subjects affected / exposed	0 / 1004 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart failure with reduced ejection fraction			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Bell's palsy			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cranial nerve paralysis			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy			

subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple sclerosis			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 1004 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tension headache			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood loss anaemia			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			

Vertigo positional			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Optic ischaemic neuropathy			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastritis			
subjects affected / exposed	2 / 1004 (0.20%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	0 / 1004 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 1004 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal hernia			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			

subjects affected / exposed	0 / 1004 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biloma			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	3 / 1004 (0.30%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	4 / 1004 (0.40%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	6 / 1004 (0.60%)	1 / 201 (0.50%)	2 / 201 (1.00%)
occurrences causally related to treatment / all	4 / 6	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver injury			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Skin ulcer			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	0 / 1004 (0.00%)	1 / 201 (0.50%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Goitre			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 1004 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	2 / 1004 (0.20%)	1 / 201 (0.50%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Undifferentiated connective tissue disease			

subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac valve vegetation			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	2 / 1004 (0.20%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			

subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 1004 (0.00%)	1 / 201 (0.50%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 1004 (0.20%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 1004 (0.00%)	0 / 201 (0.00%)	1 / 201 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	1 / 1004 (0.10%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Semaglutide 7.2 mg	Placebo	Semaglutide 2.4 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	784 / 1004 (78.09%)	117 / 201 (58.21%)	140 / 201 (69.65%)
Vascular disorders			
Hypertension			
subjects affected / exposed	18 / 1004 (1.79%)	12 / 201 (5.97%)	7 / 201 (3.48%)
occurrences (all)	18	12	7
Nervous system disorders			
Dizziness			
subjects affected / exposed	63 / 1004 (6.27%)	3 / 201 (1.49%)	12 / 201 (5.97%)
occurrences (all)	82	4	14
Hyperaesthesia			
subjects affected / exposed	55 / 1004 (5.48%)	1 / 201 (0.50%)	1 / 201 (0.50%)
occurrences (all)	73	1	1
Headache			
subjects affected / exposed	99 / 1004 (9.86%)	17 / 201 (8.46%)	16 / 201 (7.96%)
occurrences (all)	137	25	26
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	112 / 1004 (11.16%)	7 / 201 (3.48%)	19 / 201 (9.45%)
occurrences (all)	153	10	21
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	62 / 1004 (6.18%)	6 / 201 (2.99%)	12 / 201 (5.97%)
occurrences (all)	92	6	17
Abdominal pain upper			
subjects affected / exposed	58 / 1004 (5.78%)	10 / 201 (4.98%)	4 / 201 (1.99%)
occurrences (all)	74	12	5
Constipation			
subjects affected / exposed	234 / 1004 (23.31%)	18 / 201 (8.96%)	39 / 201 (19.40%)
occurrences (all)	322	19	62
Diarrhoea			

subjects affected / exposed	274 / 1004 (27.29%)	26 / 201 (12.94%)	56 / 201 (27.86%)
occurrences (all)	507	39	91
Dyspepsia			
subjects affected / exposed	103 / 1004 (10.26%)	7 / 201 (3.48%)	12 / 201 (5.97%)
occurrences (all)	140	8	12
Eructation			
subjects affected / exposed	92 / 1004 (9.16%)	1 / 201 (0.50%)	16 / 201 (7.96%)
occurrences (all)	130	1	25
Gastrooesophageal reflux disease			
subjects affected / exposed	48 / 1004 (4.78%)	6 / 201 (2.99%)	13 / 201 (6.47%)
occurrences (all)	55	33	15
Nausea			
subjects affected / exposed	439 / 1004 (43.73%)	27 / 201 (13.43%)	77 / 201 (38.31%)
occurrences (all)	907	40	148
Vomiting			
subjects affected / exposed	249 / 1004 (24.80%)	14 / 201 (6.97%)	33 / 201 (16.42%)
occurrences (all)	524	23	65
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	72 / 1004 (7.17%)	3 / 201 (1.49%)	8 / 201 (3.98%)
occurrences (all)	74	3	8
Sensitive skin			
subjects affected / exposed	71 / 1004 (7.07%)	0 / 201 (0.00%)	0 / 201 (0.00%)
occurrences (all)	101	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	43 / 1004 (4.28%)	9 / 201 (4.48%)	14 / 201 (6.97%)
occurrences (all)	50	11	18
Back pain			
subjects affected / exposed	51 / 1004 (5.08%)	4 / 201 (1.99%)	14 / 201 (6.97%)
occurrences (all)	57	5	15
Infections and infestations			
COVID-19			
subjects affected / exposed	114 / 1004 (11.35%)	24 / 201 (11.94%)	21 / 201 (10.45%)
occurrences (all)	122	25	22

Nasopharyngitis			
subjects affected / exposed	82 / 1004 (8.17%)	25 / 201 (12.44%)	15 / 201 (7.46%)
occurrences (all)	117	34	21
Sinusitis			
subjects affected / exposed	35 / 1004 (3.49%)	8 / 201 (3.98%)	12 / 201 (5.97%)
occurrences (all)	40	9	15
Upper respiratory tract infection			
subjects affected / exposed	61 / 1004 (6.08%)	15 / 201 (7.46%)	13 / 201 (6.47%)
occurrences (all)	74	17	15
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	74 / 1004 (7.37%)	9 / 201 (4.48%)	10 / 201 (4.98%)
occurrences (all)	97	13	17

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 September 2022	The amendment from version 1.0 of the protocol to version 2.0 was an administrative amendment as version 1.0 of the protocol was an internal version.
04 October 2022	Key changes are listed below: - Editorial changes e.g. spelling errors, punctuation or updates to more exact wording. Discontinuation criteria line added. Crosses corrected for contraceptive counselling, attend visit fasting, anti semaglutide antibodies and administration of trial product. Two confirmatory secondary endpoints added. Number of participants increased to 400 and ran-domisation changed to 5:1:1. Figure 4-1 updated accordingly. Number of participants in the MRI subpopulation increased to 210. New criteria 8 added. New section added. New footnote added to Table 8-1. Hepatic event text deleted. New appendix added. Plan for immunogenicity analyses changed. Text added. Numbers updated.
16 February 2023	Key changes are listed below: - Editorial changes e.g. spelling errors, punctuation or updates to more exact wording. Biochemistry and haematology assessments added at V16. PHQ-9 and C-SSRS added to V8, V10, V14 and V18. Removed from V12. Handout of PK diaries at V22 removed from flowchart. Added that delaying dose escalation is allowed. Calcitonin ≥ 100 ng/L added as a discontinuation criterion. Patient Health Questionaire-9 (PHQ-9) and Columbia-Suicide Severity Rating Scale (C-SSRS) at V8, V10, V14 and V18 added to text. Removed from V12 from text. Added ‘Acute kidney injury’. Added direct bilirubin, amylase, calcitonin and lipase. Criteria for hepatic laboratory outliers added. Added ‘Acute kidney injury’. Appendix added. Slovakia requirements added.
10 August 2023	Key changes are listed below: - Editorial changes e.g. spelling errors, punctuation or updates to more exact wording. Tobacco use assessment added at end-of-treatment (V22) as new endpoint. Removal of the potential risk of 'Neoplasms’ (malignant and non-malignant) from Table 2-1. The number of randomised participants in the MRI subgroup changed from approximately 210 to 50 participants. Update of the dosage and administration of, and transition to, the new drug-device combination product during the maintenance phase. Adding text in Section 8.1.5 clarifying that data collected for the clinical assessments ‘Control of Eating Questionnaire (COEQ)’ and ‘Three Factor eating questionnaire 18-items (TFEQ-R18V2)’ at end-of-study (V23) is explorative and will not be included in the clinical study report.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Secondary endpoint “Change in free fatty acids” was removed from secondary endpoints due to lack of baseline data.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/40961952