Clinical trial results:
Investigation of safety and efficacy of NNC0174-0833 for weight management – a dose finding trial

Summary

EudraCT number	2018-001945-14
Trial protocol	GB FI DK PL
Global end of trial date	25 March 2021

Results information

Result version number	v1 (current)
This version publication date	09 February 2022
First version publication date	09 February 2022

Trial information

Trial identification

Sponsor protocol code	NN9838-4433

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03856047
WHO universal trial number (UTN)	U1111-1214-0429

Notes:

Sponsors

Sponsor organisation name	Novo Nordisk A/S
Sponsor organisation address	Novo Allé, Bagsvaerd, Denmark, 2880
Public contact	Clinical Reporting Office (1452), Novo Nordisk A/S, clinicaltrials@novonordisk.com
Scientific contact	Clinical Reporting Office (1452), 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	11 November 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 March 2020
Global end of trial reached?	Yes
Global end of trial date	25 March 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to compare the dose-response of increasing doses of NNC0174-0833 once weekly (OW) versus placebo and versus liraglutide 3.0 mg once daily (OD) on body weight, in subjects with overweight or obesity, when added as an adjunct to a reduced-calorie diet and increased physical activity.

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki (October 2013) and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Good Clinical Practice, including archiving of essential documents (November 2016), and 21 code of federal regulations (CFR) 312.120.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2019
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	Canada: 43
Country: Number of subjects enrolled	Denmark: 45
Country: Number of subjects enrolled	Finland: 86
Country: Number of subjects enrolled	United Kingdom: 78
Country: Number of subjects enrolled	Ireland: 23
Country: Number of subjects enrolled	Japan: 70
Country: Number of subjects enrolled	Poland: 60
Country: Number of subjects enrolled	Serbia: 40
Country: Number of subjects enrolled	United States: 205
Country: Number of subjects enrolled	South Africa: 56
Worldwide total number of subjects	706
EEA total number of subjects	214

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)	629
From 65 to 84 years	77
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The trial was conducted at 57 sites in 10 countries as follows: Canada (5), Denmark (2), Finland (4), Ireland (1), Japan (3), Poland (3), Serbia (5), South Africa (5), United Kingdom (7), United States of America (22).

Pre-assignment

Screening details:

Subjects were randomized in 6:1 ratio between active treatment (cagrilintide and liraglutide) arms and placebo arms. The 5 different cagrilintide placebo arms and one liraglutide placebo arm were pooled into one placebo group in the main analyses. Subjects received treatments 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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cagrilintide 0.3 mg

Arm description:

Subjects were to receive once weekly subcutaneous (s.c.) injection of 0.3 milligrams (mg) cagrilintide for 26 weeks, using NovoPen® 4 pen-injector.

Arm type	Experimental
Investigational medicinal product name	Cagrilintide
Investigational medicinal product code	NNC0174-0833 A 10 mg/mL cartridge
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were to receive once weekly s.c. injection of 0.3 mg cagrilintide for 26 weeks, using NovoPen® 4 pen-injector.

Arm title	Cagrilintide 0.6 mg

Arm description:

Subjects were to receive once weekly s.c. injection of 0.6 mg cagrilintide for 26 weeks, using NovoPen® 4 pen-injector.

Arm type	Experimental
Investigational medicinal product name	Cagrilintide
Investigational medicinal product code	NNC0174-0833 A 10 mg/mL cartridge
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were to receive once weekly s.c. injection of 0.6 mg cagrilintide for 26 weeks, using NovoPen® 4 pen-injector.

Arm title	Cagrilintide 1.2 mg

Arm description:

Subjects were to receive once weekly s.c. injection of cagrilintide for 26 weeks, using NovoPen® 4 pen-injector. Subjects initially received 0.6 mg of cagrilintide and the dose was then escalated every other

week until the target dose of 1.2 mg was reached: 0.6 mg (week 0) and 1.2 mg (week 2 to week 26).

Arm type	Experimental
Investigational medicinal product name	Cagrilintide
Investigational medicinal product code	NNC0174-0833 A 10 mg/mL cartridge
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were to receive once weekly s.c. injection of cagrilintide for 26 weeks, using NovoPen® 4 pen-injector. Subjects initially received 0.6 mg of cagrilintide and the dose was then escalated every other week until the target dose of 1.2 mg was reached: 0.6 mg (week 0) and 1.2 mg (week 2 to week 26).

Arm title	Cagrilintide 2.4 mg

Arm description:

Subjects were to receive once weekly s.c. injection of cagrilintide for 26 weeks, using NovoPen® 4 pen-injector. Subjects initially received 0.6 mg of cagrilintide and the dose was then escalated every other week until the target dose of 2.4 mg was reached: 0.6 mg (week 0), 1.2 mg (week 2), 2.4 mg (week 4 to week 26).

Arm type	Experimental
Investigational medicinal product name	Cagrilintide
Investigational medicinal product code	NNC0174-0833 A 10 mg/mL cartridge
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were to receive once weekly s.c. injection of cagrilintide for 26 weeks, using NovoPen® 4 pen-injector. Subjects initially received 0.6 mg of cagrilintide and the dose was then escalated every other week until the target dose of 2.4 mg was reached: 0.6 mg (week 0), 1.2 mg (week 2), 2.4 mg (week 4 to week 26).

Arm title	Cagrilintide 4.5 mg

Arm description:

Subjects were to receive once weekly s.c. injection of cagrilintide for 26 weeks, using NovoPen® 4 pen-injector. Subjects initially received 0.6 mg of cagrilintide and the dose was then escalated every other week until the target dose of 4.5 mg was reached: 0.6 mg (week 0), 1.2 mg (week 2), 2.4 mg (week 4), 4.5 mg (week 6 to week 26).

Arm type	Experimental
Investigational medicinal product name	Cagrilintide
Investigational medicinal product code	NNC0174-0833 A 10 mg/mL cartridge
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were to receive once weekly s.c. injection of cagrilintide for 26 weeks, using NovoPen® 4 pen-injector. Subjects initially received 0.6 mg of cagrilintide and the dose was then escalated every other week until the target dose of 4.5 mg was reached: 0.6 mg (week 0), 1.2 mg (week 2), 2.4 mg (week 4), 4.5 mg (week 6 to week 26).

Arm title	Liraglutide 3.0 mg

Arm description:

Subjects were to receive once daily s.c. injection of liraglutide for 26 weeks, using PDS290 pen-injector. Subjects initially received 0.6 mg of liraglutide and the dose was then escalated every week until the target dose of 3.0 mg was reached: 0.6 mg (week 0), 1.2 mg (week 1), 1.8 mg (week 2), 2.4 mg (week 3), 3.0 mg (week 4 to week 26).

Arm type	Experimental

Investigational medicinal product name	Liraglutide
Investigational medicinal product code	
Other name	Saxenda
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were to receive once daily s.c. injection of liraglutide for 26 weeks, using PDS290 pen-injector. Subjects initially received 0.6 mg of liraglutide and the dose was then escalated every other week until the target dose of 3.0 mg was reached: 0.6 mg (week 0), 1.2 mg (week 1), 1.8 mg (week 2), 2.4 mg (week 3), 3.0 mg (week 4 to week 26).

Arm title	Pooled placebo

Arm description:

Subjects were to receive once weekly / once daily s.c. injection of placebo matched to cagrilintide / liraglutide (0.3 mg, 0.6 mg, 1.2 mg, 2.4 mg or 4.5 mg / 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, 3.0 mg) for 26 weeks respectively.

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 were to receive once weekly / once daily s.c. injection of placebo matched to cagrilintide / liraglutide (0.3 mg, 0.6 mg, 1.2 mg, 2.4 mg or 4.5 mg / 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, 3.0 mg) for 26 weeks respectively.

Number of subjects in period 1	Cagrilintide 0.3 mg	Cagrilintide 0.6 mg	Cagrilintide 1.2 mg
Started	101	100	102
Full analysis set	101	100	102
Safety analysis set	101	100	102
Completed	97	97	98
Not completed	4	3	4
Consent withdrawn by subject	-	1	1
Lost to follow-up	4	2	3

Number of subjects in period 1	Cagrilintide 2.4 mg	Cagrilintide 4.5 mg	Liraglutide 3.0 mg
Started	102	101	99
Full analysis set	102	101	99
Safety analysis set	102	101	99
Completed	101	94	95
Not completed	1	7	4
Consent withdrawn by subject	-	3	-
Lost to follow-up	1	4	4

Number of subjects in period 1	Pooled placebo
Started	101

Full analysis set	101
Safety analysis set	101
Completed	95
Not completed	6
Consent withdrawn by subject	2
Lost to follow-up	4

Baseline characteristics

Reporting groups	
Reporting group title	Cagrilintide 0.3 mg
Reporting group description:	
Subjects were to receive once weekly subcutaneous (s.c.) injection of 0.3 milligrams (mg) cagrilintide for 26 weeks, using NovoPen® 4 pen-injector.	
Reporting group title	Cagrilintide 0.6 mg
Reporting group description:	
Subjects were to receive once weekly s.c. injection of 0.6 mg cagrilintide for 26 weeks, using NovoPen® 4 pen-injector.	
Reporting group title	Cagrilintide 1.2 mg
Reporting group description:	
Subjects were to receive once weekly s.c. injection of cagrilintide for 26 weeks, using NovoPen® 4 pen-injector. Subjects initially received 0.6 mg of cagrilintide and the dose was then escalated every other week until the target dose of 1.2 mg was reached: 0.6 mg (week 0) and 1.2 mg (week 2 to week 26).	
Reporting group title	Cagrilintide 2.4 mg
Reporting group description:	
Subjects were to receive once weekly s.c. injection of cagrilintide for 26 weeks, using NovoPen® 4 pen-injector. Subjects initially received 0.6 mg of cagrilintide and the dose was then escalated every other week until the target dose of 2.4 mg was reached: 0.6 mg (week 0), 1.2 mg (week 2), 2.4 mg (week 4 to week 26).	
Reporting group title	Cagrilintide 4.5 mg
Reporting group description:	
Subjects were to receive once weekly s.c. injection of cagrilintide for 26 weeks, using NovoPen® 4 pen-injector. Subjects initially received 0.6 mg of cagrilintide and the dose was then escalated every other week until the target dose of 4.5 mg was reached: 0.6 mg (week 0), 1.2 mg (week 2), 2.4 mg (week 4), 4.5 mg (week 6 to week 26).	
Reporting group title	Liraglutide 3.0 mg
Reporting group description:	
Subjects were to receive once daily s.c. injection of liraglutide for 26 weeks, using PDS290 pen-injector. Subjects initially received 0.6 mg of liraglutide and the dose was then escalated every week until the target dose of 3.0 mg was reached: 0.6 mg (week 0), 1.2 mg (week 1), 1.8 mg (week 2), 2.4 mg (week 3), 3.0 mg (week 4 to week 26).	
Reporting group title	Pooled placebo
Reporting group description:	
Subjects were to receive once weekly / once daily s.c. injection of placebo matched to cagrilintide / liraglutide (0.3 mg, 0.6 mg, 1.2 mg, 2.4 mg or 4.5 mg / 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, 3.0 mg) for 26 weeks respectively.	

Reporting group values	Cagrilintide 0.3 mg	Cagrilintide 0.6 mg	Cagrilintide 1.2 mg
Number of subjects	101	100	102
Age Categorical			
Units: Subjects			
Age Continuous			
Units: years			
arithmetic mean	53.5	53.2	52.1
standard deviation	± 10.3	± 11.0	± 8.7
Gender Categorical			
Units: Subjects			
Female	56	62	63
Male	45	38	39

Reporting group values	Cagrilintide 2.4 mg	Cagrilintide 4.5 mg	Liraglutide 3.0 mg
Number of subjects	102	101	99
Age Categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	52.7	51.5	51.5
standard deviation	± 9.8	± 12.7	± 9.3
Gender Categorical Units: Subjects			
Female	75	56	65
Male	27	45	34

Reporting group values	Pooled placebo	Total	
Number of subjects	101	706	
Age Categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	51.4		
standard deviation	± 11.9	-	
Gender Categorical Units: Subjects			
Female	59	436	
Male	42	270	

End points

End points reporting groups

Reporting group title	Cagrilintide 0.3 mg
Reporting group description:	
Subjects were to receive once weekly subcutaneous (s.c.) injection of 0.3 milligrams (mg) cagrilintide for 26 weeks, using NovoPen® 4 pen-injector.	

Reporting group title	Cagrilintide 0.6 mg
Reporting group description:	
Subjects were to receive once weekly s.c. injection of 0.6 mg cagrilintide for 26 weeks, using NovoPen® 4 pen-injector.	

Reporting group title	Cagrilintide 1.2 mg
Reporting group description:	
Subjects were to receive once weekly s.c. injection of cagrilintide for 26 weeks, using NovoPen® 4 pen-injector. Subjects initially received 0.6 mg of cagrilintide and the dose was then escalated every other week until the target dose of 1.2 mg was reached: 0.6 mg (week 0) and 1.2 mg (week 2 to week 26).	

Reporting group title	Cagrilintide 2.4 mg
Reporting group description:	
Subjects were to receive once weekly s.c. injection of cagrilintide for 26 weeks, using NovoPen® 4 pen-injector. Subjects initially received 0.6 mg of cagrilintide and the dose was then escalated every other week until the target dose of 2.4 mg was reached: 0.6 mg (week 0), 1.2 mg (week 2), 2.4 mg (week 4 to week 26).	

Reporting group title	Cagrilintide 4.5 mg
Reporting group description:	
Subjects were to receive once weekly s.c. injection of cagrilintide for 26 weeks, using NovoPen® 4 pen-injector. Subjects initially received 0.6 mg of cagrilintide and the dose was then escalated every other week until the target dose of 4.5 mg was reached: 0.6 mg (week 0), 1.2 mg (week 2), 2.4 mg (week 4), 4.5 mg (week 6 to week 26).	

Reporting group title	Liraglutide 3.0 mg
Reporting group description:	
Subjects were to receive once daily s.c. injection of liraglutide for 26 weeks, using PDS290 pen-injector. Subjects initially received 0.6 mg of liraglutide and the dose was then escalated every week until the target dose of 3.0 mg was reached: 0.6 mg (week 0), 1.2 mg (week 1), 1.8 mg (week 2), 2.4 mg (week 3), 3.0 mg (week 4 to week 26).	

Reporting group title	Pooled placebo
Reporting group description:	
Subjects were to receive once weekly / once daily s.c. injection of placebo matched to cagrilintide / liraglutide (0.3 mg, 0.6 mg, 1.2 mg, 2.4 mg or 4.5 mg / 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, 3.0 mg) for 26 weeks respectively.	

Primary: Change in body weight (%)

End point title	Change in body weight (%)
End point description:	
Change in body weight (%) from week 0 to week 26 is presented. For descriptive analysis and statistical analysis endpoint was evaluated based on data from in-trial period and treatment adherent period, respectively. In-trial period was defined as uninterrupted time interval from date of randomisation to date of last contact with trial site. Follow-up time for positive antibodies was not included in in-trial period. Treatment-adherent: a subject is treatment adherent until first time of non-adherence defined as: subject has not been dosed with trial product within the prior 14 days; subject has received other weight management drug or bariatric surgery; subject has not reached target dose at a pre-specified week; After the pre-specified evaluation week for the target dose, subject has not received the target dose ±10% within the prior 14 days. The full analysis set included all randomised subjects. Number of subjects analysed = Number of subjects who contributed to the analysis.	
End point type	Primary

End point timeframe:

From randomization at week 0 to week 26

End point values	Cagrilintide 0.3 mg	Cagrilintide 0.6 mg	Cagrilintide 1.2 mg	Cagrilintide 2.4 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	96	97	98	99
Units: Percentage point of body weight				
arithmetic mean (standard deviation)	-6.1 (± 3.9)	-6.9 (± 5.4)	-8.5 (± 5.4)	-9.5 (± 6.2)

End point values	Cagrilintide 4.5 mg	Liraglutide 3.0 mg	Pooled placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	97	95	95	
Units: Percentage point of body weight				
arithmetic mean (standard deviation)	-10.8 (± 5.5)	-8.5 (± 5.6)	-3.0 (± 5.2)	

Statistical analyses

Statistical analysis title	Cagrilintide 0.3 mg versus Placebo

Statistical analysis description:

Week 26 responses were analysed using an analysis of covariance (ANCOVA) model with randomised treatment as factor and baseline (week 0) body weight as covariate. For each treatment arm, multiple (x1000) imputation of intermittend missing data was done using Markov Chain Monte Carlo, followed by sequential regression for monotone missing values of body weight including sex and region as factors.

Comparison groups	Cagrilintide 0.3 mg v Pooled placebo
Number of subjects included in analysis	191
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	= 0.0002
Method	ANCOVA
Parameter estimate	Treatment difference (%-points)
Point estimate	-2.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.58
upper limit	-1.4
Variability estimate	Standard error of the mean
Dispersion value	0.81

Notes:

[1] - Erroneously, database auto-calculated the total number of subjects. The subjects in this analysis were 202.

Statistical analysis title	Cagrilintide 0.6 mg versus Placebo

Statistical analysis description:

Week 26 responses were analysed using an analysis of covariance model with randomised treatment as factor and baseline (week 0) body weight as covariate. For each treatment arm, multiple (x1000) imputation of intermittend missing data was done using Markov Chain Monte Carlo, followed by sequential regression for monotone missing values of body weight including sex and region as factors.

Comparison groups	Cagrilintide 0.6 mg v Pooled placebo
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Treatment difference (%-points)
Point estimate	-3.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.38
upper limit	-2.17
Variability estimate	Standard error of the mean
Dispersion value	0.82

Notes:

[2] - Erroneously, database auto-calculated the total number of subjects. The subjects in this analysis were 201.

Statistical analysis title	Cagrilintide 1.2 mg versus Placebo

Statistical analysis description:

Week 26 responses were analysed using an analysis of covariance model with randomised treatment as factor and baseline (week 0) body weight as covariate. For each treatment arm, multiple (x1000) imputation of intermittend missing data was done using Markov Chain Monte Carlo, followed by sequential regression for monotone missing values of body weight including sex and region as factors.

Comparison groups	Cagrilintide 1.2 mg v Pooled placebo
Number of subjects included in analysis	193
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Treatment difference (%-points)
Point estimate	-6.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.77
upper limit	-4.36
Variability estimate	Standard error of the mean
Dispersion value	0.87

Notes:

[3] - Erroneously, database auto-calculated the total number of subjects. The subjects in this analysis were 203.

Statistical analysis title	Cagrilintide 2.4 mg versus Placebo

Statistical analysis description:

Week 26 responses were analysed using an analysis of covariance model with randomised treatment as factor and baseline (week 0) body weight as covariate. For each treatment arm, multiple (x1000) imputation of intermittend missing data was done using Markov Chain Monte Carlo, followed by sequential regression for monotone missing values of body weight including sex and region as factors.

Comparison groups	Cagrilintide 2.4 mg v Pooled placebo
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority[4]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Treatment difference (%-points)
Point estimate	-6.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.28
upper limit	-5.09
Variability estimate	Standard error of the mean
Dispersion value	0.81

Notes:

[4] - Erroneously, database auto-calculated the total number of subjects. The subjects in this analysis were 203.

Statistical analysis title	Cagrilintide 4.5 mg versus Placebo

Statistical analysis description:

Week 26 responses were analysed using an analysis of covariance model with randomised treatment as factor and baseline (week 0) body weight as covariate. For each treatment arm, multiple (x1000) imputation of intermittend missing data was done using Markov Chain Monte Carlo, followed by sequential regression for monotone missing values of body weight including sex and region as factors.

Comparison groups	Cagrilintide 4.5 mg v Pooled placebo
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	superiority[5]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Treatment difference (%-points)
Point estimate	-7.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.42
upper limit	-6.16
Variability estimate	Standard error of the mean
Dispersion value	0.83

Notes:

[5] - Erroneously, database auto-calculated the total number of subjects. The subjects in this analysis were 202.

Statistical analysis title	Liraglutide 3.0 mg versus Placebo

Statistical analysis description:

Week 26 responses were analysed using an analysis of covariance model with randomised treatment as factor and baseline (week 0) body weight as covariate. For each treatment arm, multiple (x1000) imputation of intermittend missing data was done using Markov Chain Monte Carlo, followed by sequential regression for monotone missing values of body weight including sex and region as factors.

Comparison groups	Liraglutide 3.0 mg v Pooled placebo

Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority[6]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Treatment difference (%-points)
Point estimate	-5.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.61
upper limit	-4.35
Variability estimate	Standard error of the mean
Dispersion value	0.83

Notes:

[6] - Erroneously, database auto-calculated the total number of subjects. The subjects in this analysis were 200.

Statistical analysis title	Cagrilintide 0.3 mg Versus Liraglutide 3.0 mg

Statistical analysis description:

Week 26 responses were analysed using an analysis of covariance model with randomised treatment as factor and baseline (week 0) body weight as covariate. For each treatment arm, multiple (x1000) imputation of intermittend missing data was done using Markov Chain Monte Carlo, followed by sequential regression for monotone missing values of body weight including sex and region as factors.

Comparison groups	Cagrilintide 0.3 mg v Liraglutide 3.0 mg
Number of subjects included in analysis	191
Analysis specification	Pre-specified
Analysis type	superiority[7]
P-value	= 0.0003
Method	ANCOVA
Parameter estimate	Treatment difference (%-points)
Point estimate	2.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.38
upper limit	4.6
Variability estimate	Standard error of the mean
Dispersion value	0.82

Notes:

[7] - Erroneously, database auto-calculated the total number of subjects. The subjects in this analysis were 200.

Statistical analysis title	Cagrilintide 0.6 mg Versus Liraglutide 3.0 mg

Statistical analysis description:

Week 26 responses were analysed using an analysis of covariance model with randomised treatment as factor and baseline (week 0) body weight as covariate. For each treatment arm, multiple (x1000) imputation of intermittend missing data was done using Markov Chain Monte Carlo, followed by sequential regression for monotone missing values of body weight including sex and region as factors.

Comparison groups	Cagrilintide 0.6 mg v Liraglutide 3.0 mg

Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	superiority[8]
P-value	= 0.0082
Method	ANCOVA
Parameter estimate	Treatment difference (%-points)
Point estimate	2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	3.84
Variability estimate	Standard error of the mean
Dispersion value	0.83

Notes:

[8] - Erroneously, database auto-calculated the total number of subjects. The subjects in this analysis were 199.

Statistical analysis title	Cagrilintide 1.2 mg Versus Liraglutide 3.0 mg

Statistical analysis description:

Week 26 responses were analysed using an analysis of covariance model with randomised treatment as factor and baseline (week 0) body weight as covariate. For each treatment arm, multiple (x1000) imputation of intermittend missing data was done using Markov Chain Monte Carlo, followed by sequential regression for monotone missing values of body weight including sex and region as factors.

Comparison groups	Cagrilintide 1.2 mg v Liraglutide 3.0 mg
Number of subjects included in analysis	193
Analysis specification	Pre-specified
Analysis type	superiority[9]
P-value	= 0.9209
Method	ANCOVA
Parameter estimate	Treatment difference (%-points)
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.82
upper limit	1.64
Variability estimate	Standard error of the mean
Dispersion value	0.88

Notes:

[9] - Erroneously, database auto-calculated the total number of subjects. The subjects in this analysis were 201.

Statistical analysis title	Cagrilintide 2.4 mg Versus Liraglutide 3.0 mg

Statistical analysis description:

Week 26 responses were analysed using an analysis of covariance model with randomised treatment as factor and baseline (week 0) body weight as covariate. For each treatment arm, multiple (x1000) imputation of intermittend missing data was done using Markov Chain Monte Carlo, followed by sequential regression for monotone missing values of body weight including sex and region as factors.

Comparison groups	Cagrilintide 2.4 mg v Liraglutide 3.0 mg

Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority[10]
P-value	= 0.396
Method	ANCOVA
Parameter estimate	Treatment difference (%-points)
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.33
upper limit	0.92
Variability estimate	Standard error of the mean
Dispersion value	0.83

Notes:

[10] - Erroneously, database auto-calculated the total number of subjects. The subjects in this analysis were 201.

Statistical analysis title	Cagrilintide 4.5 mg Verus Liraglutide 3.0 mg

Statistical analysis description:

Week 26 responses were analysed using an analysis of covariance model with randomised treatment as factor and baseline (week 0) body weight as covariate. For each treatment arm, multiple (x1000) imputation of intermittend missing data was done using Markov Chain Monte Carlo, followed by sequential regression for monotone missing values of body weight including sex and region as factors.

Comparison groups	Cagrilintide 4.5 mg v Liraglutide 3.0 mg
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	superiority[11]
P-value	= 0.0316
Method	ANCOVA
Parameter estimate	Treatment difference (%-points)
Point estimate	-1.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.46
upper limit	-0.16
Variability estimate	Standard error of the mean
Dispersion value	0.84

Notes:

[11] - Erroneously, database auto-calculated the total number of subjects. The subjects in this analysis were 200.

Secondary: Subjects who achieve (yes/no) body weight reduction more than or equal to 5% from randomisation

End point title	Subjects who achieve (yes/no) body weight reduction more than or equal to 5% from randomisation

End point description:

Percentage of subjects who achieved a weight loss of greater than or equal to (≥) 5% of baseline (week 0) body weight at 26 weeks is presented. The full analysis set included all randomised participants. Number of subjects analysed = Number of subjects who contributed to the analysis.

End point type	Secondary

End point timeframe:

After 26 weeks

End point values	Cagrilintide 0.3 mg	Cagrilintide 0.6 mg	Cagrilintide 1.2 mg	Cagrilintide 2.4 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	83	82	72	80
Units: Percentage of subjects				
number (not applicable)	57.47	61.98	75.84	74.12

End point values	Cagrilintide 4.5 mg	Liraglutide 3.0 mg	Pooled placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	80	78	79	
Units: Percentage of subjects				
number (not applicable)	88.74	76.16	30.90	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HbA1c (%-point)

End point title	Change in HbA1c (%-point)

End point description:

Change in HbA1c (measured as percentage point of HbA1c) from week 0 to week 26 is presented. The endpoint was evaluated based on the data from in-trial period. In-trial period was defined as the uninterrupted time interval from date of randomisation to date of last contact with trial site. Follow-up time for positive antibodies was not included in the in-trial period. The full analysis set included all randomised subjects. Number of subjects analysed = Number of subjects who contributed to the analysis.

End point type	Secondary

End point timeframe:

From randomization at week 0 to week 26

End point values	Cagrilintide 0.3 mg	Cagrilintide 0.6 mg	Cagrilintide 1.2 mg	Cagrilintide 2.4 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	97	95	99
Units: Percentage point of HbA1c				
arithmetic mean (standard deviation)	0.0 (± 0.2)	-0.1 (± 0.2)	-0.1 (± 0.3)	-0.1 (± 0.3)

End point values	Cagrilintide 4.5 mg	Liraglutide 3.0 mg	Pooled placebo	

Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95	95	94	
Units: Percentage point of HbA1c				
arithmetic mean (standard deviation)	-0.1 (± 0.2)	-0.3 (± 0.2)	-0.1 (± 0.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in HbA1c (mmol/mol)

End point title	Change in HbA1c (mmol/mol)

End point description:

Change in HbA1c from week 0 to week 26 is presented. The endpoint was evaluated based on the data from in-trial period. In-trial period was defined as the uninterrupted time interval from date of randomisation to date of last contact with trial site. Follow-up time for positive antibodies was not included in the in-trial period. The full analysis set included all randomised subjects. Number of subjects analysed = Number of subjects who contributed to the analysis.

End point type	Secondary

End point timeframe:

From randomization at week 0 to week 26

End point values	Cagrilintide 0.3 mg	Cagrilintide 0.6 mg	Cagrilintide 1.2 mg	Cagrilintide 2.4 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	97	95	99
Units: millimoles per mole (mmol/mol)				
arithmetic mean (standard deviation)	-0.5 (± 2.4)	-0.6 (± 2.2)	-0.8 (± 3.0)	-1.0 (± 2.9)

End point values	Cagrilintide 4.5 mg	Liraglutide 3.0 mg	Pooled placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95	95	94	
Units: millimoles per mole (mmol/mol)				
arithmetic mean (standard deviation)	-1.2 (± 2.4)	-2.9 (± 2.7)	-0.6 (± 2.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of treatment emergent adverse events (TEAEs)

End point title	Number of treatment emergent adverse events (TEAEs)

End point description:

An adverse event (AE) was any untoward medical occurrence in a clinical trial participant administered

or used a medicinal product, whether or not considered related to the medicinal product or usage. All AEs reported here are TEAEs. TEAE is defined as an event that had onset date during the on-treatment period. The endpoint was evaluated based on the data from on-treatment period which started from the date of first trial product administration to date of last trial product administration excluding potential off-treatment time intervals triggered by at least 6 consecutive missed doses for cagrilintide or 6 consecutive weeks of missed dosing with liraglutide. The safety analysis set included all randomized subjects exposed to at least one dose of randomized treatment.

End point type	Secondary

End point timeframe:

From randomisation at week 0 to week 32 (‘end of trial’)

End point values	Cagrilintide 0.3 mg	Cagrilintide 0.6 mg	Cagrilintide 1.2 mg	Cagrilintide 2.4 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	100	102	102
Units: Events	335	291	361	449

End point values	Cagrilintide 4.5 mg	Liraglutide 3.0 mg	Pooled placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	101	99	101	
Units: Events	460	470	276	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From week 0 to week 32
Results are based on the safety analysis set which included all randomised subjects exposed to at least one dose of randomised treatment. All presented adverse events are treatment emergent adverse events (TEAEs).

Adverse event reporting additional description:

TEAE is defined as an event that had onset during on-treatment period which started from date of first trial product administration to date of last trial product administration excluding potential off-treatment time intervals triggered by at least 6 consecutive missed doses for cagrilintide or 6 consecutive weeks of missed dosing with liraglutide.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23

Reporting groups

Reporting group title	Cagrilintide 1.2 mg

Reporting group description:

Subjects were to receive once weekly s.c. injection of cagrilintide for 26 weeks, using NovoPen® 4 pen-injector. Subjects initially received 0.6 mg of cagrilintide and the dose was then escalated every other week until the target dose of 1.2 mg was reached: 0.6 mg (week 0) and 1.2 mg (week 2 to week 26).

Reporting group title	Cagrilintide 0.6 mg

Reporting group description:

Subjects were to receive once weekly s.c. injection of 0.6 mg cagrilintide for 26 weeks, using NovoPen® 4 pen-injector.

Reporting group title	Cagrilintide 0.3 mg

Reporting group description:

Subjects were to receive once weekly s.c. injection of 0.3 mg cagrilintide for 26 weeks, using NovoPen® 4 pen-injector.

Reporting group title	Liraglutide 3.0 mg

Reporting group description:

Subjects were to receive once daily s.c. injection of liraglutide for 26 weeks, using PDS290 pen-injector. Subjects initially received 0.6 mg of liraglutide and the dose was then escalated every week until the target dose of 3.0 mg was reached: 0.6 mg (week 0), 1.2 mg (week 1), 1.8 mg (week 2), 2.4 mg (week 3), 3.0 mg (week 4 to week 26).

Reporting group title	Cagrilintide 4.5 mg

Reporting group description:

Subjects were to receive once weekly s.c. injection of cagrilintide for 26 weeks, using NovoPen® 4 pen-injector. Subjects initially received 0.6 mg of cagrilintide and the dose was then escalated every other week until the target dose of 4.5 mg was reached: 0.6 mg (week 0), 1.2 mg (week 2), 2.4 mg (week 4), 4.5 mg (week 6 to week 26).

Reporting group title	Placebo Pool

Reporting group description:

Subjects were to receive once weekly / once daily s.c. injection of placebo matched to cagrilintide / liraglutide (0.3 mg, 0.6 mg, 1.2 mg, 2.4 mg or 4.5 mg / 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, 3.0 mg) for 26 weeks respectively.

Reporting group title	Cagrilintide 2.4 mg

Reporting group description:

Subjects were to receive once weekly s.c. injection of cagrilintide for 26 weeks, using NovoPen® 4 pen-injector. Subjects initially received 0.6 mg of cagrilintide and the dose was then escalated every other week until the target dose of 2.4 mg was reached: 0.6 mg (week 0), 1.2 mg (week 2), 2.4 mg (week 4 to week 26).

Serious adverse events	Cagrilintide 1.2 mg	Cagrilintide 0.6 mg	Cagrilintide 0.3 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 102 (6.86%)	2 / 100 (2.00%)	6 / 101 (5.94%)
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)			
Gallbladder adenoma			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			
subjects affected / exposed	1 / 102 (0.98%)	0 / 100 (0.00%)	0 / 101 (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
Rectal adenocarcinoma			
subjects affected / exposed	0 / 102 (0.00%)	1 / 100 (1.00%)	0 / 101 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 100 (0.00%)	0 / 101 (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 disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	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 / 102 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 102 (0.98%)	0 / 100 (0.00%)	0 / 101 (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
Pulmonary oedema			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Ligament injury			
subjects affected / exposed	0 / 102 (0.00%)	1 / 100 (1.00%)	0 / 101 (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
Meniscus injury			
subjects affected / exposed	0 / 102 (0.00%)	1 / 100 (1.00%)	0 / 101 (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
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 102 (0.98%)	0 / 100 (0.00%)	0 / 101 (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
Syncope			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Deficiency anaemia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal hernia			

subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	1 / 102 (0.98%)	0 / 100 (0.00%)	0 / 101 (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
Cholelithiasis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	1 / 102 (0.98%)	0 / 100 (0.00%)	0 / 101 (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
Intervertebral disc disorder			
subjects affected / exposed	1 / 102 (0.98%)	0 / 100 (0.00%)	0 / 101 (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
Osteoarthritis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
Arthritis bacterial			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 102 (0.98%)	0 / 100 (0.00%)	0 / 101 (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			
Hypokalaemia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Liraglutide 3.0 mg	Cagrilintide 4.5 mg	Placebo Pool
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 99 (4.04%)	4 / 101 (3.96%)	3 / 101 (2.97%)
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)			
Gallbladder adenoma			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			

subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	2 / 101 (1.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	0 / 101 (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
Investigations			
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ligament injury			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			

subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	0 / 101 (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			
Deficiency anaemia			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	0 / 101 (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			
Biliary colic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	1 / 99 (1.01%)	1 / 101 (0.99%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	1 / 99 (1.01%)	0 / 101 (0.00%)	0 / 101 (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
Infections and infestations			
Arthritis bacterial			
subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	0 / 101 (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
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			

subjects affected / exposed	0 / 99 (0.00%)	1 / 101 (0.99%)	0 / 101 (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
Pneumonia			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 99 (0.00%)	0 / 101 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cagrilintide 2.4 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 102 (2.94%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gallbladder adenoma			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal adenocarcinoma			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	1 / 102 (0.98%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Non-cardiac chest pain				
subjects affected / exposed	0 / 102 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Asthma				
subjects affected / exposed	0 / 102 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	1 / 102 (0.98%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	1 / 102 (0.98%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	1 / 102 (0.98%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	1 / 102 (0.98%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				

subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Ligament injury			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meniscus injury			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			

subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Deficiency anaemia			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			

subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc disorder			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Arthritis bacterial			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pilonidal cyst			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Cagrilintide 1.2 mg	Cagrilintide 0.6 mg	Cagrilintide 0.3 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	72 / 102 (70.59%)	58 / 100 (58.00%)	59 / 101 (58.42%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	8 / 102 (7.84%)	2 / 100 (2.00%)	8 / 101 (7.92%)
occurrences (all)	9	2	10
Headache			
subjects affected / exposed	11 / 102 (10.78%)	5 / 100 (5.00%)	10 / 101 (9.90%)
occurrences (all)	13	5	15
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	8 / 102 (7.84%)	5 / 100 (5.00%)	8 / 101 (7.92%)
occurrences (all)	9	5	8
Injection site erythema			
subjects affected / exposed	6 / 102 (5.88%)	4 / 100 (4.00%)	5 / 101 (4.95%)
occurrences (all)	6	5	5
Injection site pruritus			
subjects affected / exposed	4 / 102 (3.92%)	2 / 100 (2.00%)	5 / 101 (4.95%)
occurrences (all)	4	2	6
Injection site rash			
subjects affected / exposed	2 / 102 (1.96%)	3 / 100 (3.00%)	0 / 101 (0.00%)
occurrences (all)	4	3	0
Injection site reaction			
subjects affected / exposed	7 / 102 (6.86%)	4 / 100 (4.00%)	4 / 101 (3.96%)
occurrences (all)	30	10	26
Gastrointestinal disorders			

Abdominal distension			
subjects affected / exposed	2 / 102 (1.96%)	1 / 100 (1.00%)	3 / 101 (2.97%)
occurrences (all)	2	1	3
Abdominal pain			
subjects affected / exposed	4 / 102 (3.92%)	5 / 100 (5.00%)	2 / 101 (1.98%)
occurrences (all)	5	5	3
Abdominal pain upper			
subjects affected / exposed	6 / 102 (5.88%)	1 / 100 (1.00%)	2 / 101 (1.98%)
occurrences (all)	6	1	2
Constipation			
subjects affected / exposed	8 / 102 (7.84%)	9 / 100 (9.00%)	11 / 101 (10.89%)
occurrences (all)	8	9	12
Diarrhoea			
subjects affected / exposed	8 / 102 (7.84%)	10 / 100 (10.00%)	15 / 101 (14.85%)
occurrences (all)	9	12	22
Dry mouth			
subjects affected / exposed	1 / 102 (0.98%)	0 / 100 (0.00%)	2 / 101 (1.98%)
occurrences (all)	1	0	2
Dyspepsia			
subjects affected / exposed	3 / 102 (2.94%)	2 / 100 (2.00%)	3 / 101 (2.97%)
occurrences (all)	3	2	4
Nausea			
subjects affected / exposed	37 / 102 (36.27%)	27 / 100 (27.00%)	20 / 101 (19.80%)
occurrences (all)	45	32	26
Vomiting			
subjects affected / exposed	5 / 102 (4.90%)	6 / 100 (6.00%)	6 / 101 (5.94%)
occurrences (all)	5	7	6
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 102 (2.94%)	5 / 100 (5.00%)	1 / 101 (0.99%)
occurrences (all)	3	6	1
Pain in extremity			
subjects affected / exposed	2 / 102 (1.96%)	2 / 100 (2.00%)	0 / 101 (0.00%)
occurrences (all)	2	2	0
Infections and infestations			

Nasopharyngitis			
subjects affected / exposed	13 / 102 (12.75%)	9 / 100 (9.00%)	6 / 101 (5.94%)
occurrences (all)	14	12	7
Upper respiratory tract infection			
subjects affected / exposed	6 / 102 (5.88%)	3 / 100 (3.00%)	4 / 101 (3.96%)
occurrences (all)	7	4	5
Urinary tract infection			
subjects affected / exposed	3 / 102 (2.94%)	7 / 100 (7.00%)	1 / 101 (0.99%)
occurrences (all)	3	9	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	8 / 102 (7.84%)	9 / 100 (9.00%)	4 / 101 (3.96%)
occurrences (all)	8	9	4

Non-serious adverse events	Liraglutide 3.0 mg	Cagrilintide 4.5 mg	Placebo Pool
Total subjects affected by non-serious adverse events			
subjects affected / exposed	65 / 99 (65.66%)	76 / 101 (75.25%)	45 / 101 (44.55%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	5 / 99 (5.05%)	9 / 101 (8.91%)	3 / 101 (2.97%)
occurrences (all)	11	12	7
Headache			
subjects affected / exposed	13 / 99 (13.13%)	7 / 101 (6.93%)	12 / 101 (11.88%)
occurrences (all)	24	10	22
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	8 / 99 (8.08%)	20 / 101 (19.80%)	3 / 101 (2.97%)
occurrences (all)	8	21	3
Injection site erythema			
subjects affected / exposed	3 / 99 (3.03%)	17 / 101 (16.83%)	0 / 101 (0.00%)
occurrences (all)	3	22	0
Injection site pruritus			
subjects affected / exposed	3 / 99 (3.03%)	7 / 101 (6.93%)	0 / 101 (0.00%)
occurrences (all)	3	7	0
Injection site rash			
subjects affected / exposed	2 / 99 (2.02%)	6 / 101 (5.94%)	0 / 101 (0.00%)
occurrences (all)	2	8	0

Injection site reaction			
subjects affected / exposed	1 / 99 (1.01%)	10 / 101 (9.90%)	0 / 101 (0.00%)
occurrences (all)	1	39	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	5 / 99 (5.05%)	2 / 101 (1.98%)	2 / 101 (1.98%)
occurrences (all)	5	2	3
Abdominal pain			
subjects affected / exposed	4 / 99 (4.04%)	5 / 101 (4.95%)	1 / 101 (0.99%)
occurrences (all)	4	5	1
Abdominal pain upper			
subjects affected / exposed	7 / 99 (7.07%)	2 / 101 (1.98%)	3 / 101 (2.97%)
occurrences (all)	9	2	3
Constipation			
subjects affected / exposed	26 / 99 (26.26%)	21 / 101 (20.79%)	7 / 101 (6.93%)
occurrences (all)	30	25	10
Diarrhoea			
subjects affected / exposed	18 / 99 (18.18%)	7 / 101 (6.93%)	9 / 101 (8.91%)
occurrences (all)	28	9	10
Dry mouth			
subjects affected / exposed	5 / 99 (5.05%)	0 / 101 (0.00%)	0 / 101 (0.00%)
occurrences (all)	6	0	0
Dyspepsia			
subjects affected / exposed	10 / 99 (10.10%)	4 / 101 (3.96%)	4 / 101 (3.96%)
occurrences (all)	10	4	4
Nausea			
subjects affected / exposed	39 / 99 (39.39%)	47 / 101 (46.53%)	18 / 101 (17.82%)
occurrences (all)	56	61	26
Vomiting			
subjects affected / exposed	20 / 99 (20.20%)	8 / 101 (7.92%)	3 / 101 (2.97%)
occurrences (all)	31	8	4
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 99 (2.02%)	6 / 101 (5.94%)	7 / 101 (6.93%)
occurrences (all)	4	6	8
Pain in extremity			

subjects affected / exposed	2 / 99 (2.02%)	1 / 101 (0.99%)	7 / 101 (6.93%)
occurrences (all)	2	1	7
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	10 / 99 (10.10%)	3 / 101 (2.97%)	10 / 101 (9.90%)
occurrences (all)	12	3	12
Upper respiratory tract infection			
subjects affected / exposed	7 / 99 (7.07%)	6 / 101 (5.94%)	3 / 101 (2.97%)
occurrences (all)	8	7	5
Urinary tract infection			
subjects affected / exposed	4 / 99 (4.04%)	2 / 101 (1.98%)	2 / 101 (1.98%)
occurrences (all)	4	2	2
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	9 / 99 (9.09%)	17 / 101 (16.83%)	4 / 101 (3.96%)
occurrences (all)	10	18	4

Non-serious adverse events	Cagrilintide 2.4 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	62 / 102 (60.78%)		
Nervous system disorders			
Dizziness			
subjects affected / exposed	9 / 102 (8.82%)		
occurrences (all)	14		
Headache			
subjects affected / exposed	11 / 102 (10.78%)		
occurrences (all)	17		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	10 / 102 (9.80%)		
occurrences (all)	12		
Injection site erythema			
subjects affected / exposed	7 / 102 (6.86%)		
occurrences (all)	23		
Injection site pruritus			
subjects affected / exposed	7 / 102 (6.86%)		
occurrences (all)	11		

Injection site rash subjects affected / exposed occurrences (all)	0 / 102 (0.00%) 0		
Injection site reaction subjects affected / exposed occurrences (all)	12 / 102 (11.76%) 44		
Gastrointestinal disorders Abdominal distension subjects affected / exposed occurrences (all)	6 / 102 (5.88%) 7		
Abdominal pain subjects affected / exposed occurrences (all)	3 / 102 (2.94%) 4		
Abdominal pain upper subjects affected / exposed occurrences (all)	4 / 102 (3.92%) 4		
Constipation subjects affected / exposed occurrences (all)	17 / 102 (16.67%) 17		
Diarrhoea subjects affected / exposed occurrences (all)	18 / 102 (17.65%) 20		
Dry mouth subjects affected / exposed occurrences (all)	2 / 102 (1.96%) 3		
Dyspepsia subjects affected / exposed occurrences (all)	3 / 102 (2.94%) 3		
Nausea subjects affected / exposed occurrences (all)	32 / 102 (31.37%) 41		
Vomiting subjects affected / exposed occurrences (all)	9 / 102 (8.82%) 11		
Musculoskeletal and connective tissue disorders			

Arthralgia subjects affected / exposed occurrences (all) Pain in extremity subjects affected / exposed occurrences (all)	6 / 102 (5.88%) 7 1 / 102 (0.98%) 1		
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all) Urinary tract infection subjects affected / exposed occurrences (all)	 4 / 102 (3.92%) 7 2 / 102 (1.96%) 2 4 / 102 (3.92%) 5		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	 13 / 102 (12.75%) 13		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/34798060