Clinical trial results:
A Phase 3, Randomized, Open-Label Trial Comparing Efficacy and Safety of Tirzepatide versus Semaglutide Once Weekly as Add-on Therapy to Metformin in Patients with Type 2 Diabetes (SURPASS-2)

Summary

EudraCT number	2018-004422-29
Trial protocol	GB
Global end of trial date	15 February 2021

Results information

Result version number	v1 (current)
This version publication date	06 February 2022
First version publication date	06 February 2022

Trial information

Trial identification

Sponsor protocol code	I8F-MC-GPGL

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03987919
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 17001

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 8772854559,

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	15 February 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 February 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The reason for this study is to compare the effect of the study drug tirzepatide to semaglutide on blood sugar levels in participants with type 2 diabetes. The study will last approximately 47 weeks and may include about 12 visits.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 July 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	Australia: 46
Country: Number of subjects enrolled	Brazil: 147
Country: Number of subjects enrolled	Canada: 59
Country: Number of subjects enrolled	Argentina: 640
Country: Number of subjects enrolled	Israel: 87
Country: Number of subjects enrolled	Mexico: 352
Country: Number of subjects enrolled	Puerto Rico: 19
Country: Number of subjects enrolled	United States: 456
Country: Number of subjects enrolled	United Kingdom: 72
Worldwide total number of subjects	1878
EEA total number of subjects	0

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)	1420
From 65 to 84 years	456
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

1879 participants were randomized in to the study and only 1878 participants received at least one dose of study drug.

Pre-assignment

Screening details:

No Text Available

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	5 mg Tirzepatide

Arm description:

5 milligrams (mg) tirzepatide administered subcutaneously (SC) once a week.

Arm type	Experimental
Investigational medicinal product name	Tirzepatide
Investigational medicinal product code	
Other name	LY3298176
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

5 mg tirzepatide administered SC once a week.

Arm title	10 mg Tirzepatide

Arm description:

10 mg tirzepatide administered SC once a week.

Arm type	Experimental
Investigational medicinal product name	Tirzepatide
Investigational medicinal product code	
Other name	LY3298176
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

10 mg tirzepatide administered SC once a week.

Arm title	15 mg Tirzepatide

Arm description:

15 mg tirzepatide administered SC once a week.

Arm type	Experimental
Investigational medicinal product name	Tirzepatide
Investigational medicinal product code	
Other name	LY3298176
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

15 mg tirzepatide administered SC once a week.

Arm title	1 mg Semaglutide

Arm description:

1 mg semaglutide administered SC once a week.

Arm type	Active comparator
Investigational medicinal product name	Semaglutide
Investigational medicinal product code	
Other name	Ozempic
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

1 mg semaglutide administered SC once a week.

Number of subjects in period 1	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide
Started	470	469	470
Received at least one dose of study drug	470	469	470
Completed	451	442	446
Not completed	19	27	24
Adverse event, serious fatal	4	4	4
Consent withdrawn by subject	7	7	8
Physician decision	-	2	-
Study terminated by Sponsor	-	-	-
Adverse event, non-fatal	1	4	1
Other – as reported by the investigator	1	3	2
Pregnancy	1	-	1
Lost to follow-up	5	6	8
Protocol deviation	-	1	-

Number of subjects in period 1	1 mg Semaglutide
Started	469
Received at least one dose of study drug	469
Completed	443
Not completed	26
Adverse event, serious fatal	1
Consent withdrawn by subject	4
Physician decision	4
Study terminated by Sponsor	1

Adverse event, non-fatal	3
Other – as reported by the investigator	-
Pregnancy	1
Lost to follow-up	12
Protocol deviation	-

Baseline characteristics

Reporting groups	
Reporting group title	5 mg Tirzepatide
Reporting group description:	
5 milligrams (mg) tirzepatide administered subcutaneously (SC) once a week.	
Reporting group title	10 mg Tirzepatide
Reporting group description:	
10 mg tirzepatide administered SC once a week.	
Reporting group title	15 mg Tirzepatide
Reporting group description:	
15 mg tirzepatide administered SC once a week.	
Reporting group title	1 mg Semaglutide
Reporting group description:	
1 mg semaglutide administered SC once a week.	

Reporting group values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide
Number of subjects	470	469	470
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	56.3	57.2	55.9
standard deviation	± 10.0	± 10.5	± 10.4
Gender categorical Units: Subjects			
Female	265	231	256
Male	205	238	214
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	325	322	334
Not Hispanic or Latino	145	147	136
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	53	53	57
Asian	6	11	5
Native Hawaiian or Other Pacific Islander	0	0	1

Black or African American	28	21	15
White	382	376	392
More than one race	1	8	0
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
Argentina	158	160	161
Australia	12	11	12
Brazil	37	37	36
Canada	15	15	14
Israel	22	22	22
Mexico	89	87	88
Puerto Rico	6	4	6
United Kingdom	18	18	18
United States	113	115	113
Hemoglobin A1c			
HbA1c is the glycosylated fraction of hemoglobin A. HbA1c is measured primarily to identify average plasma glucose concentration over prolonged periods of time.			
Units: Percentage of HbA1c			
arithmetic mean	8.32	8.30	8.26
standard deviation	± 1.08	± 1.02	± 1.00

Reporting group values	1 mg Semaglutide	Total	
Number of subjects	469	1878	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	56.9		
standard deviation	± 10.8	-	
Gender categorical Units: Subjects			
Female	244	996	
Male	225	882	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	336	1317	
Not Hispanic or Latino	133	561	
Unknown or Not Reported	0	0	
Race (NIH/OMB) Units: Subjects			

American Indian or Alaska Native	45	208	
Asian	3	25	
Native Hawaiian or Other Pacific Islander	2	3	
Black or African American	15	79	
White	401	1551	
More than one race	3	12	
Unknown or Not Reported	0	0	
Region of Enrollment Units: Subjects			
Argentina	161	640	
Australia	11	46	
Brazil	37	147	
Canada	15	59	
Israel	21	87	
Mexico	88	352	
Puerto Rico	3	19	
United Kingdom	18	72	
United States	115	456	
Hemoglobin A1c			
HbA1c is the glycosylated fraction of hemoglobin A. HbA1c is measured primarily to identify average plasma glucose concentration over prolonged periods of time.			
Units: Percentage of HbA1c			
arithmetic mean	8.25		
standard deviation	± 1.01	-	

End points

End points reporting groups

Reporting group title	5 mg Tirzepatide
Reporting group description:	
5 milligrams (mg) tirzepatide administered subcutaneously (SC) once a week.	
Reporting group title	10 mg Tirzepatide
Reporting group description:	
10 mg tirzepatide administered SC once a week.	
Reporting group title	15 mg Tirzepatide
Reporting group description:	
15 mg tirzepatide administered SC once a week.	
Reporting group title	1 mg Semaglutide
Reporting group description:	
1 mg semaglutide administered SC once a week.	

Primary: Change from Baseline in Hemoglobin A1c (HbA1c) (10 mg and 15 mg)

End point title	Change from Baseline in Hemoglobin A1c (HbA1c) (10 mg and 15 mg)[1]

End point description:

HbA1c is the glycosylated fraction of hemoglobin A. HbA1c is measured primarily to identify average plasma glucose concentration over prolonged periods of time. Least Squares (LS) mean was determined by mixed-model repeated measures (MMRM) model with Baseline + Pooled Country + Treatment + Time + Treatment*Time (Type III sum of squares).

Analysis Population Description (APD): All participants who received at least one dose of study drug and had a baseline and at least 1 post-baseline HbA1c value, excluding patients who discontinued study drug due to inadvertent enrollment and data after initiating rescue antihyperglycemic medication or prematurely stopping study drug.

End point type	Primary

End point timeframe:

Baseline, Week 40

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: Per SAP, this outcome is planned to compare 10 mg Tirzepatide and 15 mg Tirzepatide with 1 mg Semaglutide.

End point values	10 mg Tirzepatide	15 mg Tirzepatide	1 mg Semaglutide	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	459	464	461	
Units: Percentage of HbA1c				
least squares mean (standard error)	-2.37 (± 0.048)	-2.46 (± 0.048)	-1.86 (± 0.048)	

Statistical analyses

Statistical analysis title	Change from Baseline in Hemoglobin A1c (HbA1c)
Comparison groups	10 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	920
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.64
upper limit	-0.38

Statistical analysis title	Change from Baseline in Hemoglobin A1c (HbA1c)
Comparison groups	15 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	925
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.73
upper limit	-0.47

Secondary: Change from Baseline in HbA1c (5 mg)

End point title	Change from Baseline in HbA1c (5 mg)[2]

End point description:

HbA1c is the glycosylated fraction of hemoglobin A. HbA1c is measured primarily to identify average plasma glucose concentration over prolonged periods of time. Least Squares (LS) mean was determined by mixed-model repeated measures (MMRM) model with Baseline + Pooled Country + Treatment + Time + Treatment*Time (Type III sum of squares).

APD: All participants who received at least one dose of study drug and had a baseline and at least 1 post-baseline HbA1c value, excluding patients who discontinued study drug due to inadvertent enrollment and data after initiating rescue antihyperglycemic medication or prematurely stopping study drug.

End point type	Secondary

End point timeframe:

Baseline, Week 40

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: Per SAP, this outcome is planned to compare 5 mg Tirzepatide with 1 mg Semaglutide.

End point values	5 mg Tirzepatide	1 mg Semaglutide		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	461	461		
Units: Percentage of HbA1c				
least squares mean (standard error)	-2.09 (± 0.047)	-1.86 (± 0.048)		

Statistical analyses

Statistical analysis title	Change from Baseline in HbA1c (5 mg)
Comparison groups	5 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	922
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.36
upper limit	-0.1

Secondary: Change from Baseline in Body Weight

End point title	Change from Baseline in Body Weight

End point description:

Least Squares (LS) mean was determined by mixed-model repeated measures (MMRM) model with Baseline + Pooled Country + Baseline HbA1c Group (<=8.5%, >8.5%) + Treatment + Time + Treatment*Time (Type III sum of squares).

APD: All participants who received at least one dose of study drug and had a baseline and at least 1 post-baseline body weight value, excluding patients who discontinued study drug due to inadvertent enrollment and data after initiating rescue antihyperglycemic medication or prematurely stopping study drug.

End point type	Secondary

End point timeframe:

Baseline, Week 40

End point values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide	1 mg Semaglutide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	461	459	464	462
Units: Kilograms (kg)				
least squares mean (standard error)	-7.8 (± 0.33)	-10.3 (± 0.34)	-12.4 (± 0.34)	-6.2 (± 0.33)

Statistical analyses

Statistical analysis title	Change from Baseline in Body Weight
Comparison groups	5 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	923
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	-0.7

Statistical analysis title	Change from Baseline in Body Weight
Comparison groups	10 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5
upper limit	-3.2

Statistical analysis title	Change from Baseline in Body Weight
Comparison groups	15 mg Tirzepatide v 1 mg Semaglutide

Number of subjects included in analysis	926
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-6.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	-5.3

Secondary: Percentage of Participants Achieving an HbA1c Target Value of <7%

End point title	Percentage of Participants Achieving an HbA1c Target Value of <7%

End point description:

Hemoglobin A1c (HbA1c) is the glycosylated fraction of hemoglobin A. HbA1c is measured to identify average plasma glucose concentration over prolonged periods of time.

APD: All participants who received at least one dose of study drug and had a baseline and at least 1 post-baseline HbA1c value, excluding patients who discontinued study drug due to inadvertent enrollment and data after initiating rescue antihyperglycemic medication or prematurely stopping study drug.

End point type	Secondary

End point timeframe:

Week 40

End point values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide	1 mg Semaglutide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	461	459	464	461
Units: Percentage of Participants				
number (not applicable)	85.47	88.89	92.24	81.13

Statistical analyses

Statistical analysis title	Percentage of Participants Achieving an HbA1c <7%
Comparison groups	5 mg Tirzepatide v 1 mg Semaglutide

Number of subjects included in analysis	922
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.023
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.06
upper limit	2.23

Statistical analysis title	Percentage of Participants Achieving an HbA1c <7%
Comparison groups	10 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	920
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.44
upper limit	3.17

Statistical analysis title	Percentage of Participants Achieving an HbA1c <7%
Comparison groups	15 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	925
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.97
upper limit	4.66

Secondary: Change from Baseline in Fasting Serum Glucose

End point title	Change from Baseline in Fasting Serum Glucose

End point description:

Change from Baseline in Fasting Serum Glucose. Least Squares (LS) mean was determined by mixed-model repeated measures (MMRM) model with Baseline + Pooled Country + Baseline HbA1c Group (<=8.5%, >8.5%) + Treatment + Time + Treatment*Time (Type III sum of squares).

APD: All participants who received at least one dose of study drug and had a baseline and at least 1 post-baseline FSG value, excluding patients who discontinued study drug due to inadvertent enrollment and data after initiating rescue antihyperglycemic medication or prematurely stopping study drug.

End point type	Secondary

End point timeframe:

Baseline, Week 40

End point values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide	1 mg Semaglutide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	461	458	464	459
Units: milligram per Deciliter (mg/dL)				
least squares mean (standard error)	-56.0 (± 1.57)	-61.6 (± 1.60)	-63.4 (± 1.59)	-48.6 (± 1.58)

Statistical analyses

Statistical analysis title	Change from Baseline in Fasting Serum Glucose
Comparison groups	5 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	920
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-7.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.7
upper limit	-3

Statistical analysis title	Change from Baseline in Fasting Serum Glucose
Comparison groups	10 mg Tirzepatide v 1 mg Semaglutide

Number of subjects included in analysis	917
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.4
upper limit	-8.6

Statistical analysis title	Change from Baseline in Fasting Serum Glucose
Comparison groups	15 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	923
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-14.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.1
upper limit	-10.3

Secondary: Mean Change from Baseline in Daily Average 7-Point Self-Monitored Blood Glucose (SMBG) Values

End point title	Mean Change from Baseline in Daily Average 7-Point Self-Monitored Blood Glucose (SMBG) Values

End point description:

The self-monitored plasma glucose (SMBG) data were collected at the following 7 time points: Morning Premeal - Fasting, Morning 2-hour Postmeal, Midday Premeal, Midday 2-hour Postmeal, Evening Premeal, Evening 2-hour Postmeal and Bedtime. Least Squares (LS) mean was determined by mixed-model repeated measures (MMRM) model with Baseline + Pooled Country + Baseline HbA1c Group (<=8.5%, >8.5%) + Treatment + Time + Treatment*Time (Type III sum of squares).

APD: All participants who received at least one dose of study drug and had a baseline and at least 1 post-baseline SMBG value, excluding patients who discontinued study drug due to inadvertent enrollment and data after initiating rescue antihyperglycemic medication or prematurely stopping study drug.

End point type	Secondary

End point timeframe:

Baseline, Week 40

End point values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide	1 mg Semaglutide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	424	412	413	414
Units: mg/dL				
least squares mean (standard error)	-65.4 (± 1.04)	-70.6 (± 1.05)	-74.3 (± 1.05)	-61.4 (± 1.04)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Weight Loss ≥5%

End point title	Percentage of Participants who Achieved Weight Loss ≥5%

End point description:

Percentage of Participants who Achieved Weight Loss ≥5%.
APD: All participants who received at least one dose of study drug and had a baseline and at least 1 post-baseline weight loss, excluding patients who discontinued study drug due to inadvertent enrollment and data after initiating rescue antihyperglycemic medication or prematurely stopping study drug.

End point type	Secondary

End point timeframe:

Week 40

End point values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide	1 mg Semaglutide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	461	459	464	462
Units: Percentage of Participants				
number (not applicable)	68.55	82.35	86.21	58.44

Statistical analyses

Statistical analysis title	Weight Loss ≥5%
Comparison groups	5 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	923
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.58

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.2
upper limit	2.08

Statistical analysis title	Weight Loss ≥5%
Comparison groups	10 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.57
upper limit	4.75

Statistical analysis title	Weight Loss ≥5%
Comparison groups	15 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	926
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.32
upper limit	6.38

Secondary: Diabetes Treatment Satisfaction as Measured by the Diabetes Treatment Satisfaction Questionnaire, Change Version (DTSQc) Hyperglycemia, Hypoglycemia and Total Score

End point title	Diabetes Treatment Satisfaction as Measured by the Diabetes Treatment Satisfaction Questionnaire, Change Version (DTSQc) Hyperglycemia, Hypoglycemia and Total Score

End point description:

DTSQc, an 8-item questionnaire, assesses relative change in treatment satisfaction perceived frequency of hyperglycemia, and perceived frequency of hypoglycemia from baseline to week 40 or early

termination. The questionnaire consists of 8 items, 6 of which (1 and 4 through 8) assess treatment satisfaction. Each item is rated on a 7-point Likert scale. The scores from the 6 treatment satisfaction items are summed to a Total Treatment Satisfaction Score, which ranges from -18 to 18 where the higher the score the greater the improvement in satisfaction with treatment. The lower the score the greater the deterioration in satisfaction with treatment. The hyperglycemia and hypoglycemia scores range from -3 to 3 where negative scores indicate fewer problems with blood glucose levels and positive scores indicate more problems than before. LS Mean was determined by ANCOVA with Baseline DTSQs + Pooled Country + Baseline HbA1c Group (<=8.5%, >8.5%) + Treatment (Type III sum of squares).

End point type	Secondary
End point timeframe:	
Baseline, Week 40	

End point values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide	1 mg Semaglutide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	419[3]	399[4]	398	412[5]
Units: Units on a Scale				
least squares mean (standard error)				
Hyperglycemia	-1.3 (± 0.10)	-1.4 (± 0.10)	-1.5 (± 0.10)	-1.1 (± 0.10)
Hypoglycemia	-0.7 (± 0.10)	-0.7 (± 0.10)	-0.8 (± 0.10)	-0.7 (± 0.10)
Total Score	15.7 (± 0.18)	15.6 (± 0.19)	16.1 (± 0.19)	15.8 (± 0.19)

Notes:

[3] - Hyperglycemia: 418
Hypoglycemia: 416
Total Score: 419

[4] - Hyperglycemia: 399
Hypoglycemia: 398
Total Score: 399

[5] - Hyperglycemia: 411
Hypoglycemia: 412
Total Score: 411

Statistical analyses

Statistical analysis title	DTSQc
Statistical analysis description:	
Hyperglycemia	
Comparison groups	5 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	831
Analysis specification	Pre-specified
Analysis type	superiority[6]
P-value	= 0.084
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	0.03

Notes:
[6] - Hyperglycemia

Statistical analysis title	DTSQc
Statistical analysis description: Hyperglycemia	
Comparison groups	10 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	811
Analysis specification	Pre-specified
Analysis type	superiority[7]
P-value	= 0.05
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.54
upper limit	0

Notes:
[7] - Hyperglycemia

Statistical analysis title	DTSQc
Statistical analysis description: Hyperglycemia	
Comparison groups	15 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	810
Analysis specification	Pre-specified
Analysis type	superiority[8]
P-value	= 0.005
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.66
upper limit	-0.12

Notes:
[8] - Hyperglycemia

Statistical analysis title	DTSQc
Statistical analysis description: Hypoglycemia	
Comparison groups	5 mg Tirzepatide v 1 mg Semaglutide

Number of subjects included in analysis	831
Analysis specification	Pre-specified
Analysis type	superiority[9]
P-value	= 0.688
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.33
upper limit	0.22

Notes:

[9] - Hypoglycemia

Statistical analysis title	DTSQc
Statistical analysis description: Hypoglycemia	
Comparison groups	10 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	811
Analysis specification	Pre-specified
Analysis type	superiority[10]
P-value	= 0.909
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.29
upper limit	0.26

Notes:

[10] - Hypoglycemia

Statistical analysis title	DTSQc
Statistical analysis description: Hypoglycemia	
Comparison groups	15 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	810
Analysis specification	Pre-specified
Analysis type	superiority[11]
P-value	= 0.358
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	0.15

Notes:
[11] - Hypoglycemia

Statistical analysis title	DTSQc
Statistical analysis description:	
Total Score	
Comparison groups	5 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	831
Analysis specification	Pre-specified
Analysis type	superiority[12]
P-value	= 0.701
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.62
upper limit	0.41

Notes:
[12] - Total Score

Statistical analysis title	DTSQc
Statistical analysis description:	
Total Score	
Comparison groups	10 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	811
Analysis specification	Pre-specified
Analysis type	superiority[13]
P-value	= 0.341
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.78
upper limit	0.27

Notes:
[13] - Total Score

Statistical analysis title	DTSQc
Comparison groups	15 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	810
Analysis specification	Pre-specified
Analysis type	superiority[14]
P-value	= 0.321
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	0.26

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.26
upper limit	0.79

Notes:

[14] - Total Score

Secondary: Rate of Hypoglycemia with Blood Glucose <54 milligram/deciliter (mg/dL) [<3.0 millimole/liter (mmol/L)] or Severe Hypoglycemia

End point title	Rate of Hypoglycemia with Blood Glucose <54 milligram/deciliter (mg/dL) [<3.0 millimole/liter (mmol/L)] or Severe Hypoglycemia

End point description:

The hypoglycemia events were defined by participant reported events with blood glucose <54mg/dL) (<3.0 mmol/L] or severe hypoglycemia. Severe hypoglycemia is defined as an episode with severe cognitive impairment requiring the assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions. These episodes may be associated with sufficient neuroglycopenia to induce seizure or coma. The rate of postbaseline hypoglycemia was estimated by negative binomial model: number of episodes = Pooled Country + Baseline HbA1c Group (<=8.5%, >8.5%) + Treatment.

APD: All randomized participants who received at least one dose of study drug.

End point type	Secondary

End point timeframe:

Baseline through Safety Follow-Up (Up to Week 44)

End point values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide	1 mg Semaglutide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	470	469	470	469
Units: Episodes/participant/365.25 days				
arithmetic mean (standard error)	0.0102 (± 0.00423)	0.0046 (± 0.00488)	0.0202 (± 0.00840)	0.0046 (± 0.00340)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving an HbA1c Target Value of <5.7%

End point title	Percentage of Participants Achieving an HbA1c Target Value of <5.7%

End point description:

Percentage of Participants Achieving an HbA1c Target Value of <5.7%.

APD: All randomized participants who received at least one dose of study drug and had a baseline and at least 1 post-baseline HbA1c value, excluding patients discontinuing study drug due to inadvertent enrollment and data after initiating rescue antihyperglycemic medication or prematurely stopping study drug

End point type	Secondary
End point timeframe: Week 40	

End point values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide	1 mg Semaglutide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	461	459	464	461
Units: Percentage of Participants				
number (not applicable)	29.28	44.66	50.86	19.74

Statistical analyses

Statistical analysis title	HbA1c Target Value of <5.7%
Comparison groups	10 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	920
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.88
upper limit	5.39

Statistical analysis title	HbA1c Target Value of <5.7%
Comparison groups	15 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	925
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	5.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.73
upper limit	6.97

Statistical analysis title	HbA1c Target Value of <5.7%
Comparison groups	5 mg Tirzepatide v 1 mg Semaglutide
Number of subjects included in analysis	922
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.35
upper limit	2.57

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline, Safety follow-up (44 Weeks)

Adverse event reporting additional description:

All randomized participants who received at least one dose of study drug. Gender specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups

Reporting group title	5 mg Tirzepatide

Reporting group description:

5 mg tirzepatide administered subcutaneously (SC) once a week.

Reporting group title	15 mg Tirzepatide

Reporting group description:

15 mg tirzepatide administered SC once a week.

Reporting group title	1 mg Semaglutide

Reporting group description:

1 mg of semaglutide administered SC once a week.

Reporting group title	10 mg Tirzepatide

Reporting group description:

10 mg tirzepatide administered SC once a week.

Serious adverse events	5 mg Tirzepatide	15 mg Tirzepatide	1 mg Semaglutide
Total subjects affected by serious adverse events			
subjects affected / exposed	33 / 470 (7.02%)	27 / 470 (5.74%)	13 / 469 (2.77%)
number of deaths (all causes)	4	4	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
endometrial adenocarcinoma			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed[1]	1 / 265 (0.38%)	0 / 256 (0.00%)	0 / 244 (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
glioblastoma multiforme			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
lung carcinoma cell type unspecified stage iii			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
metastatic squamous cell carcinoma			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
non-hodgkin's lymphoma			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	1 / 469 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal cell carcinoma			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
uterine leiomyoma			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed[2]	0 / 265 (0.00%)	1 / 256 (0.39%)	0 / 244 (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
uterine neoplasm			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed[3]	1 / 265 (0.38%)	0 / 256 (0.00%)	0 / 244 (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
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
hypertension			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	1 / 469 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
orthostatic hypotension			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
peripheral vascular disorder			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	1 / 469 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
venous thrombosis limb			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	1 / 469 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
abdominal hernia repair			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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			
chest pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
death			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
sudden death			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
Reproductive system and breast disorders			
metrorrhagia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed[4]	1 / 265 (0.38%)	0 / 256 (0.00%)	0 / 244 (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
uterine prolapse			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed[5]	0 / 265 (0.00%)	0 / 256 (0.00%)	1 / 244 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	1 / 469 (0.21%)
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			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
dyspnoea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
pleural effusion			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 470 (0.21%)	1 / 470 (0.21%)	0 / 469 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
respiratory failure			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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			
post-traumatic stress disorder			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	1 / 469 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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			
amylase increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
coronavirus test positive			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
lipase increased			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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			
ankle fracture			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
femur fracture			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
hip fracture			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	1 / 469 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intentional overdose			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
ligament injury			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
multiple injuries			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
traumatic amputation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
upper limb fracture			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
wrist fracture			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 470 (0.43%)	2 / 470 (0.43%)	0 / 469 (0.00%)
occurrences causally related to treatment / all	0 / 3	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
angina unstable			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
atrial fibrillation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 470 (0.43%)	0 / 470 (0.00%)	0 / 469 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial flutter			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
cardiac failure			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
cardio-respiratory arrest			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	1 / 470 (0.21%)	0 / 469 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
ventricular tachycardia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	1 / 469 (0.21%)
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			
cerebellar infarction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
cerebrovascular accident			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	2 / 470 (0.43%)	0 / 469 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
headache			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
ischaemic stroke			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	1 / 469 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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			
retinal vein occlusion			

alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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 pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
abdominal pain upper			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	1 / 470 (0.21%)	0 / 469 (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
constipation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
epiploic appendagitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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 haemorrhage			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
inguinal hernia, obstructive			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
irritable bowel syndrome			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
lower gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
nausea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
strangulated umbilical hernia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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			
cholecystitis acute			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 470 (0.21%)	2 / 470 (0.43%)	0 / 469 (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
Skin and subcutaneous tissue disorders			
diabetic ulcer			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
end stage renal disease			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
nephrolithiasis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
urinary tract obstruction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
Endocrine disorders			
acromegaly			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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			
back pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	1 / 469 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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			
appendicitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
bacteraemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	1 / 469 (0.21%)
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			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	1 / 469 (0.21%)
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			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	2 / 470 (0.43%)	2 / 470 (0.43%)	4 / 469 (0.85%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
cellulitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
cholecystitis infective			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
complicated appendicitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
dengue fever			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
epididymitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed[6]	1 / 205 (0.49%)	0 / 214 (0.00%)	0 / 225 (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
escherichia bacteraemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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

lower respiratory tract infection alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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 alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (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
pharyngeal abscess alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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 alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	1 / 470 (0.21%)	1 / 469 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	0 / 470 (0.00%)	0 / 469 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
sepsis alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
suspected covid-19 alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	0 / 470 (0.00%)	0 / 469 (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
urosepsis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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
hypoglycaemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 470 (0.21%)	1 / 470 (0.21%)	0 / 469 (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
hyponatraemia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 470 (0.00%)	1 / 470 (0.21%)	0 / 469 (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

Serious adverse events	10 mg Tirzepatide		
Total subjects affected by serious adverse events			
subjects affected / exposed	25 / 469 (5.33%)		
number of deaths (all causes)	4		

number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
endometrial adenocarcinoma			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed[1]	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
glioblastoma multiforme			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
lung carcinoma cell type unspecified stage iii			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
metastatic squamous cell carcinoma			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 469 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
non-hodgkin's lymphoma			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

renal cell carcinoma				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 469 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
squamous cell carcinoma of skin				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
uterine leiomyoma				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed[2]	0 / 231 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
uterine neoplasm				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed[3]	0 / 231 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
deep vein thrombosis				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hypertension				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
orthostatic hypotension				
alternative dictionary used: MedDRA 23.1				

subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
peripheral vascular disorder			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
venous thrombosis limb			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
abdominal hernia repair			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 469 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
death			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pyrexia			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sudden death				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 469 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Reproductive system and breast disorders				
metrorrhagia				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed[4]	0 / 231 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
uterine prolapse				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed[5]	0 / 231 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
asthma				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
chronic obstructive pulmonary disease				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 469 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
dyspnoea				
alternative dictionary used: MedDRA 23.1				

subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pleural effusion				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pulmonary embolism				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
respiratory failure				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
post-traumatic stress disorder				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
suicide attempt				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
amylase increased				
alternative dictionary used: MedDRA 23.1				

subjects affected / exposed	1 / 469 (0.21%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
coronavirus test positive				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lipase increased				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 469 (0.21%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
ankle fracture				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 469 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
femur fracture				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hip fracture				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
intentional overdose				
alternative dictionary used: MedDRA 23.1				

subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ligament injury				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 469 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
multiple injuries				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
traumatic amputation				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
upper limb fracture				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
wrist fracture				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 469 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
acute myocardial infarction				
alternative dictionary used: MedDRA 23.1				

subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
angina unstable				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 469 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
atrial fibrillation				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
atrial flutter				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cardiac failure				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cardio-respiratory arrest				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
coronary artery disease				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

ventricular tachycardia				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
cerebellar infarction				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cerebrovascular accident				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
headache				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ischaemic stroke				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
syncope				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 469 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
anaemia				
alternative dictionary used: MedDRA 23.1				

subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
retinal vein occlusion			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 469 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
abdominal pain upper			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
constipation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
epiploic appendagitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 469 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
inguinal hernia, obstructive			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
irritable bowel syndrome			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 469 (0.21%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
lower gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
nausea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 469 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
strangulated umbilical hernia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
vomiting			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 469 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Hepatobiliary disorders			
cholecystitis acute			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 469 (0.43%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
diabetic ulcer			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
end stage renal disease			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 469 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
nephrolithiasis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 469 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
urinary tract obstruction			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			

acromegaly				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
back pain				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
osteoarthritis				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
appendicitis				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bacteraemia				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 469 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
covid-19				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 469 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
covid-19 pneumonia				

alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	2 / 469 (0.43%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
cellulitis				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 469 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
cholecystitis infective				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 469 (0.21%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
complicated appendicitis				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
dengue fever				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
epididymitis				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed[6]	0 / 238 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
escherichia bacteraemia				
alternative dictionary used: MedDRA 23.1				

subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
lower respiratory tract infection			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
osteomyelitis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pharyngeal abscess			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 469 (0.21%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
pneumonia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pyelonephritis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
sepsis			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 469 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

suspected covid-19				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
urinary tract infection				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	2 / 469 (0.43%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
urosepsis				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
dehydration				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hypoglycaemia				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hyponatraemia				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 469 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

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

Non-serious adverse events	5 mg Tirzepatide	15 mg Tirzepatide	1 mg Semaglutide
Total subjects affected by non-serious adverse events			
subjects affected / exposed	170 / 470 (36.17%)	202 / 470 (42.98%)	172 / 469 (36.67%)
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	14 / 470 (2.98%)	24 / 470 (5.11%)	24 / 469 (5.12%)
occurrences (all)	16	30	29
constipation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	31 / 470 (6.60%)	21 / 470 (4.47%)	27 / 469 (5.76%)
occurrences (all)	35	23	32
diarrhoea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	62 / 470 (13.19%)	65 / 470 (13.83%)	54 / 469 (11.51%)
occurrences (all)	120	102	68
dyspepsia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	34 / 470 (7.23%)	43 / 470 (9.15%)	31 / 469 (6.61%)
occurrences (all)	46	51	42
nausea			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	82 / 470 (17.45%)	104 / 470 (22.13%)	84 / 469 (17.91%)
occurrences (all)	110	136	126
vomiting			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	27 / 470 (5.74%)	46 / 470 (9.79%)	39 / 469 (8.32%)
occurrences (all)	35	61	53
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	35 / 470 (7.45%)	42 / 470 (8.94%)	25 / 469 (5.33%)
occurrences (all)	38	51	26

Non-serious adverse events	10 mg Tirzepatide		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	187 / 469 (39.87%)		
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	20 / 469 (4.26%)		
occurrences (all)	25		
constipation			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	21 / 469 (4.48%)		
occurrences (all)	23		
diarrhoea			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	77 / 469 (16.42%)		
occurrences (all)	98		
dyspepsia			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	29 / 469 (6.18%)		
occurrences (all)	43		
nausea			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	90 / 469 (19.19%)		
occurrences (all)	121		
vomiting			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	39 / 469 (8.32%)		
occurrences (all)	54		
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	34 / 469 (7.25%)		
occurrences (all)	43		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 June 2020	Protocol (b): Added language about the mobile (inhome) healthcare visits.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported