



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 | Argentina: 640 |
| 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 | Israel: 87 |
| Country: Number of subjects enrolled | Mexico: 352 |
| Country: Number of subjects enrolled | Puerto Rico: 19 |
| Country: Number of subjects enrolled | United Kingdom: 72 |
| Country: Number of subjects enrolled | United States: 456 |
| 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 ($\leq 8.5\%$, $> 8.5\%$) + 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 ($\leq 8.5\%$, $> 8.5\%$) + 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 ($\leq 8.5\%$, $> 8.5\%$) + 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 $\geq 5\%$ |
| 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 $\geq 5\%$ |
| 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 ($\leq 8.5\%$, $> 8.5\%$) + 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 (\pm 0.10) | -1.4 (\pm 0.10) | -1.5 (\pm 0.10) | -1.1 (\pm 0.10) |
| Hypoglycemia | -0.7 (\pm 0.10) | -0.7 (\pm 0.10) | -0.8 (\pm 0.10) | -0.7 (\pm 0.10) |
| Total Score | 15.7 (\pm 0.18) | 15.6 (\pm 0.19) | 16.1 (\pm 0.19) | 15.8 (\pm 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 occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 469 (0.21%) 0 / 1 0 / 0 | | | |
| squamous cell carcinoma of skin alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 469 (0.00%) 0 / 0 0 / 0 | | | |
| uterine leiomyoma alternative dictionary used: MedDRA 23.1 subjects affected / exposed ^[2] occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 231 (0.00%) 0 / 0 0 / 0 | | | |
| uterine neoplasm alternative dictionary used: MedDRA 23.1 subjects affected / exposed ^[3] occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 231 (0.00%) 0 / 0 0 / 0 | | | |
| Vascular disorders deep vein thrombosis alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 469 (0.00%) 0 / 0 0 / 0 | | | |
| hypertension alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 469 (0.00%) 0 / 0 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 occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 469 (0.00%) 0 / 0 0 / 0 | | |
| Nervous system disorders cerebellar infarction alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 469 (0.00%) 0 / 0 0 / 0 | | |
| cerebrovascular accident alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 469 (0.00%) 0 / 0 0 / 0 | | |
| headache alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 469 (0.00%) 0 / 0 0 / 0 | | |
| ischaemic stroke alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 469 (0.00%) 0 / 0 0 / 0 | | |
| syncope alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 469 (0.21%) 0 / 1 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 | | | |

| | | | |
|--|---|--|--|
| susppected covid-19 alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 469 (0.00%) 0 / 0 0 / 0 | | |
| urinary tract infection alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 2 / 469 (0.43%) 0 / 2 0 / 0 | | |
| urosepsis alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 469 (0.00%) 0 / 0 0 / 0 | | |
| Metabolism and nutrition disorders dehydration alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 469 (0.00%) 0 / 0 0 / 0 | | |
| hypoglycaemia alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 469 (0.00%) 0 / 0 0 / 0 | | |
| hyponatraemia alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 469 (0.00%) 0 / 0 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 occurrences (all) vomiting alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences (all) | 90 / 469 (19.19%) 121 39 / 469 (8.32%) 54 | | |
| Metabolism and nutrition disorders decreased appetite alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences (all) | 34 / 469 (7.25%) 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