Clinical trial results:
A Randomized, Double-Blind, Placebo-Controlled Phase 2 Study Comparing the Efficacy and Safety of Tirzepatide versus Placebo in Patients with Nonalcoholic Steatohepatitis (NASH)

Summary

EudraCT number	2019-001550-26
Trial protocol	GB BE FR ES IT
Global end of trial date	10 January 2024

Results information

Result version number	v1 (current)
This version publication date	25 December 2024
First version publication date	25 December 2024

Trial information

Trial identification

Sponsor protocol code	I8F-MC-GPHR

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04166773
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 17361

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, 1 877-CTLilly, EU_Lilly_Clinical_Trials@lilly.com
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-CTLilly, EU_Lilly_Clinical_Trials@lilly.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	10 January 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	10 January 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that Tirzepatide 5 milligram (mg), 10mg or 15mg administered subcutaneously (SC) once a week (QW) is superior to placebo for NASH resolution with no worsening of fibrosis at Week 52.

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	19 November 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	Poland: 1
Country: Number of subjects enrolled	Spain: 8
Country: Number of subjects enrolled	United Kingdom: 14
Country: Number of subjects enrolled	Belgium: 1
Country: Number of subjects enrolled	France: 22
Country: Number of subjects enrolled	Italy: 6
Country: Number of subjects enrolled	Israel: 5
Country: Number of subjects enrolled	Japan: 16
Country: Number of subjects enrolled	Mexico: 10
Country: Number of subjects enrolled	United States: 107
Worldwide total number of subjects	190
EEA total number of subjects	38

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)	153
From 65 to 84 years	37
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Not Applicable

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	5 mg Tirzepatide

Arm description:

Participants received 5 mg tirzepatide administered SC QW for 52 weeks [initially 2.5 mg tirzepatide SC QW for 4 weeks, then 5 mg tirzepatide SC QW from weeks 5-52].

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

Dosage and administration details:

Participants received 5 mg tirzepatide administered SC QW for 52 weeks [initially 2.5 mg tirzepatide SC QW for 4 weeks then 5 mg tirzepatide SC QW from week 5-52].

Arm title	10 mg Tirzepatide

Arm description:

Participants received 10 mg tirzepatide administered SC QW for 52 weeks [initially 2.5 mg tirzepatide SC QW for 4 weeks, then dose escalated to 5 mg, 7.5 mg, and 10 mg every 4 weeks until target dose (10 mg) was reached].

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

Dosage and administration details:

Participants received 10 mg tirzepatide administered SC QW for 52 weeks [initially 2.5 mg tirzepatide SC QW for 4 weeks, then dose escalated to 5 mg, 7.5 mg, and 10 mg every 4 weeks until target dose (10 mg) was reached].

Arm title	15 mg Tirzepatide

Arm description:

Participants received 15 mg tirzepatide administered SC QW for 52 weeks [initially 2.5 mg tirzepatide SC QW for 4 weeks, then dose escalated to 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg every 4 weeks until target dose (15 mg) was reached].

Arm type	Experimental

Investigational medicinal product name	Tirzepatide
Investigational medicinal product code	LY3298176
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 15 mg tirzepatide administered SC QW for 52 weeks [initially 2.5 mg tirzepatide SC QW for 4 weeks, then dose escalated to 5 mg, 7.5 mg, 10 mg, 12.5 mg and 15 mg every 4 weeks until target dose (15 mg) was reached].

Arm title	Placebo

Arm description:

Participants received placebo administered SC QW for 52 weeks.

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

Dosage and administration details:

Participants received placebo administered SC QW for 52 weeks.

Number of subjects in period 1	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide
Started	47	47	48
Received at Least One Dose of Study Drug	47	47	48
Completed	40	44	43
Not completed	7	3	5
Consent withdrawn by subject	1	1	2
Physician decision	-	-	-
Adverse event, non-fatal	2	-	2
Lost to follow-up	4	2	1

Number of subjects in period 1	Placebo
Started	48
Received at Least One Dose of Study Drug	48
Completed	38
Not completed	10
Consent withdrawn by subject	5
Physician decision	1
Adverse event, non-fatal	1
Lost to follow-up	3

Baseline characteristics

Reporting groups	
Reporting group title	5 mg Tirzepatide
Reporting group description:	
Participants received 5 mg tirzepatide administered SC QW for 52 weeks [initially 2.5 mg tirzepatide SC QW for 4 weeks, then 5 mg tirzepatide SC QW from weeks 5-52].	
Reporting group title	10 mg Tirzepatide
Reporting group description:	
Participants received 10 mg tirzepatide administered SC QW for 52 weeks [initially 2.5 mg tirzepatide SC QW for 4 weeks, then dose escalated to 5 mg, 7.5 mg, and 10 mg every 4 weeks until target dose (10 mg) was reached].	
Reporting group title	15 mg Tirzepatide
Reporting group description:	
Participants received 15 mg tirzepatide administered SC QW for 52 weeks [initially 2.5 mg tirzepatide SC QW for 4 weeks, then dose escalated to 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg every 4 weeks until target dose (15 mg) was reached].	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo administered SC QW for 52 weeks.	

Reporting group values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide
Number of subjects	47	47	48
Age categorical			
All randomized participants.			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	37	38	41
From 65-84 years	10	9	7
85 years and over	0	0	0
Gender categorical			
All randomized participants.			
Units: Subjects			
Female	27	26	29
Male	20	21	19
Ethnicity (NIH/OMB)			
All randomized participants.			
Units: Subjects			
Hispanic or Latino	19	15	17
Not Hispanic or Latino	21	25	27
Unknown or Not Reported	7	7	4
Race (NIH/OMB)			
All randomized participants.			
Units: Subjects			

American Indian or Alaska Native	1	1	1
Asian	5	6	6
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	41	39	41
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Region of Enrollment			
All randomized participants.			
Units: Subjects			
Belgium	0	0	1
France	7	7	2
Israel	3	2	0
Italy	1	0	2
Japan	4	4	4
Mexico	1	3	3
Poland	1	0	0
Spain	1	0	6
United Kingdom	1	5	4
United States	28	26	26

Reporting group values	Placebo	Total	
Number of subjects	48	190	
Age categorical			
All randomized participants.			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	37	153	
From 65-84 years	11	37	
85 years and over	0	0	
Gender categorical			
All randomized participants.			
Units: Subjects			
Female	27	109	
Male	21	81	
Ethnicity (NIH/OMB)			
All randomized participants.			
Units: Subjects			
Hispanic or Latino	18	69	
Not Hispanic or Latino	24	97	
Unknown or Not Reported	6	24	
Race (NIH/OMB)			
All randomized participants.			
Units: Subjects			

American Indian or Alaska Native	0	3	
Asian	5	22	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	1	
White	43	164	
More than one race	0	0	
Unknown or Not Reported	0	0	
Region of Enrollment			
All randomized participants.			
Units: Subjects			
Belgium	0	1	
France	6	22	
Israel	0	5	
Italy	3	6	
Japan	4	16	
Mexico	3	10	
Poland	0	1	
Spain	1	8	
United Kingdom	4	14	
United States	27	107	

End points

End points reporting groups

Reporting group title	5 mg Tirzepatide
Reporting group description:	
Participants received 5 mg tirzepatide administered SC QW for 52 weeks [initially 2.5 mg tirzepatide SC QW for 4 weeks, then 5 mg tirzepatide SC QW from weeks 5-52].	
Reporting group title	10 mg Tirzepatide
Reporting group description:	
Participants received 10 mg tirzepatide administered SC QW for 52 weeks [initially 2.5 mg tirzepatide SC QW for 4 weeks, then dose escalated to 5 mg, 7.5 mg, and 10 mg every 4 weeks until target dose (10 mg) was reached].	
Reporting group title	15 mg Tirzepatide
Reporting group description:	
Participants received 15 mg tirzepatide administered SC QW for 52 weeks [initially 2.5 mg tirzepatide SC QW for 4 weeks, then dose escalated to 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg every 4 weeks until target dose (15 mg) was reached].	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo administered SC QW for 52 weeks.	

Primary: Percentage of Participants With Absence of Nonalcoholic Steatohepatitis (NASH) With no Worsening of Fibrosis on Liver Histology

End point title	Percentage of Participants With Absence of Nonalcoholic Steatohepatitis (NASH) With no Worsening of Fibrosis on Liver Histology
End point description:	
NASH resolution is defined as the absence of fatty liver disease or simple steatosis without steatohepatitis; the absence of hepatocellular ballooning (nonalcoholic fatty liver disease (NAFLD) Activity Score (NAS) 0 for ballooning); with or without mild lobular inflammation (NAS 0 or 1 for inflammation); and any value for steatosis. No worsening of fibrosis is defined as no increase in fibrosis stage from baseline to Week 52. Analysis population description: All randomized participants who received at least one dose of study drug with baseline and post-baseline values and had evaluable data for this outcome prior to treatment discontinuation.	
End point type	Primary
End point timeframe:	
Week 52	

End point values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	40	35
Units: percentage of participants				
number (not applicable)	51.84	63.13	73.92	12.62

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Odds ratio, CI, and p-value for endpoint measures are from logistic regression model with baseline diabetes status, region, treatment as factors.

Comparison groups	5 mg Tirzepatide v Placebo
Number of subjects included in analysis	74
Analysis specification	Post-hoc
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	7.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.27
upper limit	24.44

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Odds ratio, CI, and p-value for endpoint measures are from logistic regression model with baseline diabetes status, region, treatment as factors.

Comparison groups	10 mg Tirzepatide v Placebo
Number of subjects included in analysis	76
Analysis specification	Post-hoc
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	11.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.59
upper limit	39.11

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Odds ratio, CI, and p-value for endpoint measures are from logistic regression model with baseline diabetes status, region, treatment as factors.

Comparison groups	15 mg Tirzepatide v Placebo

Number of subjects included in analysis	75
Analysis specification	Post-hoc
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	19.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.73
upper limit	67.25

Secondary: Percentage of Participants With ≥1 Point Decrease in Fibrosis Stage With No Worsening of NASH on Liver Histology

End point title	Percentage of Participants With ≥1 Point Decrease in Fibrosis Stage With No Worsening of NASH on Liver Histology

End point description:

NAS was derived as the unweighted sum of steatosis (0 to 3), lobular inflammation (0 to 3), and hepatocellular ballooning (0 to 2) scores. The NAS ranges from 0-8 with the higher score indicating more aggressive disease. Evaluation of fibrosis stage was based on the nonalcoholic steatohepatitis clinical research network (NASH CRN) fibrosis staging system, which was scaled from 0 to 4 stages where, 0=None to 4=Cirrhosis. Participants were evaluated with the NASH CRN scoring system with ≥1-point reduction without worsening of NASH (defined as no increase in the NAS score). APD: All randomized participants who received at least one dose of study drug with baseline and post-baseline values and had evaluable data for this outcome prior to treatment discontinuation.

End point type	Secondary

End point timeframe:

Week 52

End point values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	40	35
Units: percentage of participants				
number (not applicable)	59.21	53.35	54.3	32.51

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Odds ratio, CI, and p-value for endpoint measures are from logistic regression model with baseline diabetes status, region, treatment as factors.

Comparison groups	5 mg Tirzepatide v Placebo

Number of subjects included in analysis	74
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.025
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.15
upper limit	7.9

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Odds ratio, CI, and p-value for endpoint measures are from logistic regression model with baseline diabetes status, region, treatment as factors

Comparison groups	10 mg Tirzepatide v Placebo
Number of subjects included in analysis	76
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.074
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	6.13

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Odds ratio, CI, and p-value for endpoint measures are from logistic regression model with baseline diabetes status, region, treatment as factors.

Comparison groups	15 mg Tirzepatide v Placebo
Number of subjects included in analysis	75
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.063
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.47

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	6.4

Secondary: Percentage of Participants With ≥1 Point Increase in Fibrosis Stage on Liver Histology

End point title	Percentage of Participants With ≥1 Point Increase in Fibrosis Stage on Liver Histology

End point description:

Participants were evaluated with the NASH CRN scoring system with ≥1 stage increase in fibrosis. APD: All randomized participants who received at least one dose of study drug with baseline and post-baseline values and had evaluable data for this outcome prior to treatment discontinuation.

End point type	Secondary

End point timeframe:

Week 52

End point values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	40	35
Units: percentage of participants				
number (not applicable)	12.04	9.81	5.53	13.03

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Odds ratio, CI, and p-value for endpoint measures are from logistic regression model with baseline diabetes status, region, treatment as factors.

Comparison groups	5 mg Tirzepatide v Placebo
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.893
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.25
upper limit	3.4

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Odds ratio, CI, and p-value for endpoint measures are from logistic regression model with baseline diabetes status, region, treatment as factors.	
Comparison groups	10 mg Tirzepatide v Placebo
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.647
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.18
upper limit	2.87

Statistical analysis title	Statistical Analysis 3
Statistical analysis description: Odds ratio, CI, and p-value for endpoint measures are from logistic regression model with baseline diabetes status, region, treatment as factors.	
Comparison groups	15 mg Tirzepatide v Placebo
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.246
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.08
upper limit	1.91

Secondary: Percentage of Participants That Achieve a ≥2 Point Decrease in NAFLD (Non-alcoholic Fatty Liver Disease) Activity Score (NAS) on Liver Histology, With ≥1 Point Reduction in at Least 2 NAS Components

End point title	Percentage of Participants That Achieve a ≥2 Point Decrease in NAFLD (Non-alcoholic Fatty Liver Disease) Activity Score (NAS) on Liver Histology, With ≥1 Point Reduction in at Least 2 NAS Components

End point description:

Hepatic histological improvement in NAS was defined as a decrease (improvement) in NAS by ≥ 2 with

at least a 1-point reduction in at least 2 NAS components (lobular inflammation, hepatocellular ballooning or steatosis). The NAS was derived as the unweighted sum of steatosis (0 to 3), lobular inflammation (0 to 3), and hepatocellular ballooning (0 to 2) scores. The NAS ranges from 0-8, with the higher score indicating more aggressive disease.
APD: All randomized participants who received at least one dose of study drug with baseline and post-baseline values and had evaluable data for this outcome prior to treatment discontinuation.

End point type	Secondary

End point timeframe:

Week 52

End point values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	40	35
Units: percentage of participants				
number (not applicable)	81.02	86.55	88.77	38.09

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Odds ratio, CI, and p-value for endpoint measures are from logistic regression model with baseline diabetes status, region, treatment as factors.

Comparison groups	5 mg Tirzepatide v Placebo
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	6.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.41
upper limit	20

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Odds ratio, CI, and p-value for endpoint measures are from logistic regression model with baseline diabetes status, region, treatment as factors.

Comparison groups	10 mg Tirzepatide v Placebo

Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	10.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.36
upper limit	32.61

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Odds ratio, CI, and p-value for endpoint measures are from logistic regression model with baseline diabetes status, region, treatment as factors.

Comparison groups	15 mg Tirzepatide v Placebo
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	12.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.87
upper limit	42.65

Secondary: Mean Absolute Change From Baseline in Liver Fat Content by Magnetic Resonance Imaging – Proton Density Fat Fraction (MRI-PDFF)

End point title	Mean Absolute Change From Baseline in Liver Fat Content by Magnetic Resonance Imaging – Proton Density Fat Fraction (MRI-PDFF)

End point description:

MRI-PDFF is an established method that enables quantification of fat content in the liver. The value of whole liver fat as assessed by MRI-PDFF is expressed in percentage and ranges from 0 to 100% with higher values representing higher liver fat level. Least square (LS) mean was calculated using mixed model repeated measures (MMRM) model for post-baseline measures: Variable = Baseline + DIABFL + REGION1 + Treatment + Time + Treatment*Time (Type III sum of squares). Variance-Covariance structure (Change from Baseline) = Unstructured. APD: All randomized participants who received at least one dose of study drug with baseline and post-baseline values and had evaluable data for this outcome prior to treatment discontinuation.

End point type	Secondary

End point timeframe:

Baseline to Week 52

End point values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	33	32	27
Units: change of whole liver fat				
least squares mean (standard error)	-10.12 (± 1.165)	-10.15 (± 1.071)	-11.34 (± 1.107)	-1.31 (± 1.142)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	5 mg Tirzepatide v Placebo
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	-8.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.04
upper limit	-5.58
Variability estimate	Standard error of the mean
Dispersion value	1.632

Statistical analysis title	Statistical Analysis 2
Comparison groups	10 mg Tirzepatide v Placebo
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	-8.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.93
upper limit	-5.73
Variability estimate	Standard error of the mean
Dispersion value	1.566

Statistical analysis title	Statistical Analysis 3
Comparison groups	15 mg Tirzepatide v Placebo
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	-10.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.17
upper limit	-6.87
Variability estimate	Standard error of the mean
Dispersion value	1.591

Secondary: Mean Change From Baseline in Body Weight

End point title	Mean Change From Baseline in Body Weight

End point description:

Change in body weight at the end of 52 weeks measured in kilogram (kg) using a calibrated scale. LS mean was calculated using MMRM model for post-baseline measures: Variable = Baseline + DIABFL + REGION1 + Treatment + Time + Treatment*Time (Type III sum of squares). Variance-Covariance structure (Change from Baseline) = Unstructured. APD: All randomized participants who received at least one dose of study drug with baseline and post-baseline values and had evaluable data for this outcome prior to treatment discontinuation.

End point type	Secondary

End point timeframe:

Baseline to Week 52

End point values	5 mg Tirzepatide	10 mg Tirzepatide	15 mg Tirzepatide	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	42	42	37
Units: kilogram (kg)				
least squares mean (standard error)	-11.46 (± 1.404)	-14.22 (± 1.380)	-17.88 (± 1.376)	-1.04 (± 1.392)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	5 mg Tirzepatide v Placebo

Number of subjects included in analysis	77
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	-10.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.32
upper limit	-6.52
Variability estimate	Standard error of the mean
Dispersion value	1.976

Statistical analysis title	Statistical Analysis 2
Comparison groups	10 mg Tirzepatide v Placebo
Number of subjects included in analysis	79
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	-13.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.05
upper limit	-9.32
Variability estimate	Standard error of the mean
Dispersion value	1.96

Statistical analysis title	Statistical Analysis 3
Comparison groups	15 mg Tirzepatide v Placebo
Number of subjects included in analysis	79
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	-16.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.71
upper limit	-12.98

Variability estimate	Standard error of the mean
Dispersion value	1.957

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline Up to Week 56

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	26.1

Reporting groups

Reporting group title	5 mg Tirzepatide

Reporting group description:

Participants received 5 mg tirzepatide administered SC QW for 52 weeks [initially 2.5 mg tirzepatide SC QW for 4 weeks then 5 mg tirzepatide SC QW from weeks 5-52].

Reporting group title	Placebo

Reporting group description:

Participants received placebo administered SC QW for 52 weeks.

Reporting group title	15 mg Tirzepatide

Reporting group description:

Participants received 15 mg tirzepatide administered SC QW for 52 weeks [initially 2.5 mg tirzepatide SC QW for 4 weeks, then dose escalated to 5 mg, 7.5 mg, 10 mg, 12.5 mg and 15 mg every 4 weeks until target dose (15 mg) was reached].

Reporting group title	10 mg Tirzepatide

Reporting group description:

Participants received 10 mg tirzepatide administered SC QW for 52 weeks [initially 2.5 mg tirzepatide SC QW for 4 weeks, then dose escalated to 5 mg, 7.5 mg and 10 mg every 4 weeks until target dose (10 mg) was reached].

Serious adverse events	5 mg Tirzepatide	Placebo	15 mg Tirzepatide
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 47 (10.64%)	3 / 48 (6.25%)	0 / 48 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ovarian neoplasm			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[1]	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 29 (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
Congenital, familial and genetic disorders			

developmental hip dysplasia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (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			
phlebitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
transient ischaemic attack			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
endometrial thickening			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[2]	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
large intestine polyp			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal haemorrhage			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pneumoperitoneum			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (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
umbilical hernia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (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			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (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
Renal and urinary disorders			
ureterolithiasis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (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			
rhabdomyolysis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (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
Infections and infestations			
bacteraemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (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

covid-19 pneumonia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
hypokalaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	10 mg Tirzepatide		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 47 (8.51%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ovarian neoplasm			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[1]	0 / 26 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
developmental hip dysplasia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
phlebitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Nervous system disorders			
transient ischaemic attack			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
endometrial thickening			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[2]	0 / 26 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
large intestine polyp			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
rectal haemorrhage			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pneumoperitoneum			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
umbilical hernia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			

cholecystitis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
ureterolithiasis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
rhabdomyolysis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
bacteraemia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
covid-19 pneumonia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
hypokalaemia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at Risk 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: Gender specific events only occurring in male or female participants have had the number of participants at Risk adjusted accordingly.

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

Non-serious adverse events	5 mg Tirzepatide	Placebo	15 mg Tirzepatide
Total subjects affected by non-serious adverse events			
subjects affected / exposed	43 / 47 (91.49%)	40 / 48 (83.33%)	44 / 48 (91.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
colorectal adenoma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
hepatic adenoma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
meningioma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
ovarian neoplasm			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[3]	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
skin papilloma			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
hot flush			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
hypotension			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
orthostatic hypotension			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
peripheral coldness			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
raynaud's phenomenon			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
cyst removal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
eyelid cyst removal			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
gastrointestinal endoscopic therapy alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
hip arthroplasty alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
knee arthroplasty alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
large intestinal polypectomy alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
nail operation alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
skin neoplasm excision alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
tendon sheath incision alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
tooth extraction alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0

uterine polypectomy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[4]	0 / 27 (0.00%)	0 / 27 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 47 (6.38%)	2 / 48 (4.17%)	0 / 48 (0.00%)
occurrences (all)	3	2	0
chest discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	4
energy increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	4 / 47 (8.51%)	3 / 48 (6.25%)	5 / 48 (10.42%)
occurrences (all)	5	4	5
injection site bruising			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	2
injection site inflammation			
alternative dictionary used:			

MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
injection site pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
injection site rash			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
injection site reaction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	0 / 48 (0.00%)	2 / 48 (4.17%)
occurrences (all)	5	0	10
injection site swelling			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	1 / 48 (2.08%)	1 / 48 (2.08%)
occurrences (all)	2	1	1
non-cardiac chest pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
oedema			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
oedema peripheral			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	2 / 48 (4.17%)	0 / 48 (0.00%)
occurrences (all)	2	3	0
pyrexia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	1 / 48 (2.08%)
occurrences (all)	0	1	1
thirst			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
vaccination site pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
hypersensitivity			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	2 / 48 (4.17%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
seasonal allergy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed[5]	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
breast cyst			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
breast discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	2
intermenstrual bleeding			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[6]	0 / 27 (0.00%)	0 / 27 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
testicular pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[7]	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
vaginal haemorrhage			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[8]	0 / 27 (0.00%)	0 / 27 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
vulvovaginal discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[9]	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	2 / 48 (4.17%)
occurrences (all)	0	0	2
cough			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	2 / 47 (4.26%)	1 / 48 (2.08%)	3 / 48 (6.25%)
occurrences (all)	2	1	3
dyspnoea			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
nasal congestion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
oropharyngeal pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	2 / 48 (4.17%)	1 / 48 (2.08%)
occurrences (all)	0	2	1
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	2	1	0
depression			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	2 / 48 (4.17%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
insomnia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	1 / 48 (2.08%)
occurrences (all)	1	1	1
major depression			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
amylase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
bacterial test positive			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
blood glucose abnormal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
blood glucose decreased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
biopsy liver			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
haematocrit abnormal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
haemoglobin abnormal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
lipase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	3 / 48 (6.25%)
occurrences (all)	3	0	4
pancreatic enzymes increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
sars-cov-2 test positive			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
urine albumin/creatinine ratio increased			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
weight decreased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	5 / 47 (10.64%)	0 / 48 (0.00%)	4 / 48 (8.33%)
occurrences (all)	5	0	4
Injury, poisoning and procedural complications			
animal bite			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
epicondylitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
exposure to toxic agent			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
fibula fracture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
fall			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
immunisation reaction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	2 / 48 (4.17%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
ligament sprain			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
joint injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
meniscus injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
muscle strain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	3 / 48 (6.25%)	0 / 48 (0.00%)
occurrences (all)	1	3	0
post procedural bile leak			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
post procedural fever			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
post vaccination syndrome			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
procedural nausea			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0

rib fracture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
skin abrasion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
skin laceration			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	1 / 48 (2.08%)
occurrences (all)	0	1	2
spinal compression fracture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
stoma site haemorrhage			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
tooth fracture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
thermal burn			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
gilbert's syndrome			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Cardiac disorders			

atrial tachycardia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
bradycardia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
cardiac failure			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
palpitations			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	2	1	0
sinus bradycardia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
tachycardia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
aphasia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
disturbance in attention			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
dizziness			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	2 / 47 (4.26%)	2 / 48 (4.17%)	4 / 48 (8.33%)
occurrences (all)	2	2	4
dysgeusia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
headache			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 47 (6.38%)	5 / 48 (10.42%)	3 / 48 (6.25%)
occurrences (all)	3	5	4
hypoaesthesia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	2 / 48 (4.17%)	0 / 48 (0.00%)
occurrences (all)	1	2	0
lethargy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	2
lumbar radiculopathy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
migraine			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	2 / 48 (4.17%)	1 / 48 (2.08%)
occurrences (all)	17	2	1
neuralgia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
neuritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0

paraesthesia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
presyncope			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	2	0	1
radiculopathy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
syncope			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
somnolence			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
taste disorder			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
tension headache			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
tremor			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
lymphadenopathy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
thrombocytopenia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
tinnitus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
cataract			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	2 / 48 (4.17%)	0 / 48 (0.00%)
occurrences (all)	0	3	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
eye pain			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
meibomian gland dysfunction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
vision blurred			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
visual acuity reduced			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
abdominal distension			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 47 (6.38%)	4 / 48 (8.33%)	6 / 48 (12.50%)
occurrences (all)	3	4	8
abdominal pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	6 / 47 (12.77%)	3 / 48 (6.25%)	4 / 48 (8.33%)
occurrences (all)	12	3	7
abdominal pain lower			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	2 / 48 (4.17%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
abdominal pain upper			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	6 / 47 (12.77%)	2 / 48 (4.17%)	0 / 48 (0.00%)
occurrences (all)	10	2	0
anal fissure			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
anal incontinence			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
bowel movement irregularity			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
breath odour			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
change of bowel habit			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
colonic angioectasia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
constipation			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	11 / 47 (23.40%)	3 / 48 (6.25%)	7 / 48 (14.58%)
occurrences (all)	12	4	8
diverticulum			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0

diarrhoea			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	15 / 47 (31.91%)	11 / 48 (22.92%)	13 / 48 (27.08%)
occurrences (all)	17	14	20
dry mouth			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	3 / 48 (6.25%)	1 / 48 (2.08%)
occurrences (all)	1	3	1
duodenitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
dysphagia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
dyspepsia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	2 / 48 (4.17%)	2 / 48 (4.17%)
occurrences (all)	3	2	2
eructation			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	4 / 48 (8.33%)
occurrences (all)	1	0	5
gastric ulcer			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
flatulence			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	1 / 48 (2.08%)	3 / 48 (6.25%)
occurrences (all)	2	1	4
haemorrhoids			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
gastritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	2 / 48 (4.17%)	1 / 48 (2.08%)
occurrences (all)	0	2	1
gastrointestinal disorder			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
gastrointestinal pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	2
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	0 / 48 (0.00%)	4 / 48 (8.33%)
occurrences (all)	2	0	5
gingival bleeding			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
inguinal hernia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
large intestine polyp			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1

nausea			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	17 / 47 (36.17%)	6 / 48 (12.50%)	21 / 48 (43.75%)
occurrences (all)	69	7	26
oesophagitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
pancreatitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
rectal haemorrhage			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	1 / 48 (2.08%)
occurrences (all)	0	1	1
small intestinal obstruction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
tooth loss			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
vomiting			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 47 (6.38%)	1 / 48 (2.08%)	7 / 48 (14.58%)
occurrences (all)	3	1	14
Hepatobiliary disorders			

biliary colic			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
cholangitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
cholelithiasis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
hepatic cirrhosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	2	1	0
hepatic fibrosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
hepatic haematoma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
hypertransaminasaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	4 / 47 (8.51%)	0 / 48 (0.00%)	3 / 48 (6.25%)
occurrences (all)	4	0	5
blister			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
dermatitis contact			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
ecchymosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
eczema			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
erythema			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
intertrigo			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
koilonychia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
photosensitivity reaction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
pruritus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	2 / 48 (4.17%)	1 / 48 (2.08%)
occurrences (all)	1	2	1

rash			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	2 / 48 (4.17%)	0 / 48 (0.00%)
occurrences (all)	1	2	0
skin hyperpigmentation			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	2 / 48 (4.17%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	2 / 48 (4.17%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
microalbuminuria			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
micturition urgency			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
nephrolithiasis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
renal failure			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
renal pain			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
ureterolithiasis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
urinary incontinence			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
urine odour abnormal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
hypothyroidism			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
thyroid mass			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	5 / 47 (10.64%)	1 / 48 (2.08%)	2 / 48 (4.17%)
occurrences (all)	5	1	2
back pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	2 / 48 (4.17%)	1 / 48 (2.08%)
occurrences (all)	3	3	1
bursitis			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
exostosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
greater trochanteric pain syndrome			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
immune-mediated myositis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
joint swelling			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
limb discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
muscle spasms			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	3	0	0
myalgia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	1	1	0

neck pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
osteoarthritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
osteochondritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
osteopenia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
pain in extremity			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	1 / 48 (2.08%)	1 / 48 (2.08%)
occurrences (all)	2	1	1
osteoporosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
rhabdomyolysis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
rheumatic disorder			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
sacral pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
spinal pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
systemic lupus erythematosus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
tendonitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
acute sinusitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
bacterial vaginosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[10]	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	2 / 48 (4.17%)	0 / 48 (0.00%)
occurrences (all)	2	3	0
covid-19			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	5 / 47 (10.64%)	4 / 48 (8.33%)	9 / 48 (18.75%)
occurrences (all)	6	5	9
cellulitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
conjunctivitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
cystitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
folliculitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
fungal infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
hand-foot-and-mouth disease			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
helicobacter infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	2 / 48 (4.17%)
occurrences (all)	0	0	2

herpes virus infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
helicobacter gastritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
infected bite			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
influenza			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
lower respiratory tract infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
onychomycosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	1 / 48 (2.08%)	2 / 48 (4.17%)
occurrences (all)	1	1	2
oral fungal infection			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
otitis media			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
pharyngitis streptococcal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
respiratory tract infection viral			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
sinusitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	1 / 48 (2.08%)	1 / 48 (2.08%)
occurrences (all)	2	1	1
tooth infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	2 / 48 (4.17%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	0 / 48 (0.00%)	1 / 48 (2.08%)
occurrences (all)	2	0	1
urinary tract infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)	4 / 48 (8.33%)	2 / 48 (4.17%)
occurrences (all)	2	4	2

viral rhinitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[11]	0 / 27 (0.00%)	0 / 27 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[12]	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	9 / 47 (19.15%)	1 / 48 (2.08%)	11 / 48 (22.92%)
occurrences (all)	9	1	12
diabetes mellitus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
dyslipidaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
glucose tolerance impaired			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	3 / 48 (6.25%)	0 / 48 (0.00%)
occurrences (all)	0	3	0
hyperkalaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
hyperuricaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 48 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	3 / 48 (6.25%)	0 / 48 (0.00%)
occurrences (all)	0	3	0
vitamin d deficiency			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 48 (2.08%)	0 / 48 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	10 mg Tirzepatide		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	43 / 47 (91.49%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		

colorectal adenoma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
hepatic adenoma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
meningioma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
ovarian neoplasm			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[3]	0 / 26 (0.00%)		
occurrences (all)	0		
skin papilloma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Vascular disorders			
hot flush			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
hypertension			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 47 (6.38%)		
occurrences (all)	3		
hypotension			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
orthostatic hypotension			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
peripheral coldness			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
raynaud's phenomenon			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Surgical and medical procedures			
cyst removal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
eyelid cyst removal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
gastrointestinal endoscopic therapy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
hip arthroplasty			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
knee arthroplasty			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
large intestinal polypectomy			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	2		
nail operation			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
skin neoplasm excision			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
tendon sheath incision			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
tooth extraction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
uterine polypectomy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[4]	0 / 26 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	4 / 47 (8.51%)		
occurrences (all)	6		
chest discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
discomfort			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
energy increased				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
fatigue				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	4 / 47 (8.51%)			
occurrences (all)	5			
injection site bruising				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
injection site erythema				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
injection site inflammation				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
injection site pain				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
injection site rash				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
injection site reaction				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	2			

injection site swelling				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
malaise				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
non-cardiac chest pain				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
oedema				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
oedema peripheral				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
pain				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
pyrexia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
thirst				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
vaccination site pain				
alternative dictionary used: MedDRA 26.1				

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
hypersensitivity			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
seasonal allergy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[5]	0 / 21 (0.00%)		
occurrences (all)	0		
breast cyst			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
breast discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
intermenstrual bleeding			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[6]	0 / 26 (0.00%)		
occurrences (all)	0		
testicular pain			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed[7]	0 / 21 (0.00%)		
occurrences (all)	0		
vaginal haemorrhage			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[8]	0 / 26 (0.00%)		
occurrences (all)	0		
vulvovaginal discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[9]	0 / 26 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
cough			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
dyspnoea			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
nasal congestion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
oropharyngeal pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
depression				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
insomnia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
major depression				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Investigations				
alanine aminotransferase increased				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
amylase increased				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
bacterial test positive				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
aspartate aminotransferase increased				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
blood alkaline phosphatase increased				
alternative dictionary used: MedDRA 26.1				

subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
blood creatine phosphokinase increased				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
blood glucose abnormal				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
blood glucose decreased				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
biopsy liver				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
gamma-glutamyltransferase increased				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
haematocrit abnormal				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
haemoglobin abnormal				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
hepatic enzyme increased				
alternative dictionary used: MedDRA 26.1				

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
lipase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
pancreatic enzymes increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
sars-cov-2 test positive			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
urine albumin/creatinine ratio increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
weight decreased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 47 (6.38%)		
occurrences (all)	3		
Injury, poisoning and procedural complications			
animal bite			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
epicondylitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
exposure to toxic agent			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	3			
fibula fracture				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
fall				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
immunisation reaction				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
ligament sprain				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	2 / 47 (4.26%)			
occurrences (all)	2			
joint injury				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
meniscus injury				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
muscle strain				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	2 / 47 (4.26%)			
occurrences (all)	2			
procedural pain				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	2 / 47 (4.26%)			
occurrences (all)	2			

post procedural bile leak				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
post procedural fever				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
post vaccination syndrome				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
procedural nausea				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
rib fracture				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
skin abrasion				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
skin laceration				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
spinal compression fracture				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
stoma site haemorrhage				
alternative dictionary used: MedDRA 26.1				

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
tooth fracture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
thermal burn			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic disorders			
gilbert's syndrome			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
atrial tachycardia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
bradycardia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
cardiac failure			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
palpitations			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
sinus bradycardia			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
tachycardia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
Nervous system disorders				
aphasia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
disturbance in attention				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
dizziness				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	6 / 47 (12.77%)			
occurrences (all)	7			
dysgeusia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	2 / 47 (4.26%)			
occurrences (all)	2			
headache				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	6 / 47 (12.77%)			
occurrences (all)	7			
hypoaesthesia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
lethargy				
alternative dictionary used: MedDRA 26.1				

subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
lumbar radiculopathy				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
migraine				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
neuralgia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
neuritis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
paraesthesia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
presyncope				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
sciatica				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
radiculopathy				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			

syncope alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 47 (2.13%) 1		
somnolence alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0		
taste disorder alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	3 / 47 (6.38%) 3		
tension headache alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0		
tremor alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 47 (2.13%) 1		
Blood and lymphatic system disorders anaemia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0		
lymphadenopathy alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0		
thrombocytopenia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0		
Ear and labyrinth disorders			

tinnitus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
vertigo			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Eye disorders			
cataract			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
conjunctivitis allergic			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
eye pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
meibomian gland dysfunction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
vision blurred			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
visual acuity reduced			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			

abdominal discomfort				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	4 / 47 (8.51%)			
occurrences (all)	6			
abdominal distension				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	3 / 47 (6.38%)			
occurrences (all)	3			
abdominal pain				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	3 / 47 (6.38%)			
occurrences (all)	4			
abdominal pain lower				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
abdominal pain upper				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	2 / 47 (4.26%)			
occurrences (all)	2			
anal fissure				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
anal incontinence				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
bowel movement irregularity				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
breath odour				
alternative dictionary used: MedDRA 26.1				

subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
change of bowel habit				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
colonic angioectasia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
constipation				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	9 / 47 (19.15%)			
occurrences (all)	12			
diverticulum				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
diarrhoea				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	17 / 47 (36.17%)			
occurrences (all)	40			
dry mouth				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
duodenitis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
dysphagia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			

dyspepsia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	8 / 47 (17.02%)			
occurrences (all)	11			
eructation				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	2 / 47 (4.26%)			
occurrences (all)	2			
gastric ulcer				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
flatulence				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	3 / 47 (6.38%)			
occurrences (all)	3			
haemorrhoids				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
gastritis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
gastrointestinal disorder				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
gastrointestinal haemorrhage				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
gastrointestinal pain				
alternative dictionary used: MedDRA 26.1				

subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
gastrooesophageal reflux disease				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	3 / 47 (6.38%)			
occurrences (all)	5			
gingival bleeding				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
inguinal hernia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
large intestine polyp				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
nausea				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	16 / 47 (34.04%)			
occurrences (all)	33			
oesophagitis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	2 / 47 (4.26%)			
occurrences (all)	2			
pancreatitis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
rectal haemorrhage				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			

small intestinal obstruction				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
toothache				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
tooth loss				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
vomiting				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	3 / 47 (6.38%)			
occurrences (all)	5			
Hepatobiliary disorders				
biliary colic				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
cholangitis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
cholelithiasis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
hepatic cirrhosis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	2 / 47 (4.26%)			
occurrences (all)	2			
hepatic fibrosis				
alternative dictionary used: MedDRA 26.1				

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
hepatic haematoma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
hypertransaminasaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)		
occurrences (all)	2		
blister			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
dermatitis contact			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
ecchymosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
eczema			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
erythema			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	2		
intertrigo			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
koilonychia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
photosensitivity reaction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
pruritus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
rash			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
skin hyperpigmentation			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
urticaria			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
microalbuminuria				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
micturition urgency				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
nephrolithiasis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
renal failure				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
renal pain				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
ureterolithiasis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
urinary incontinence				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
urine odour abnormal				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			

Endocrine disorders			
hypothyroidism			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
thyroid mass			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)		
occurrences (all)	2		
back pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
bursitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
exostosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
greater trochanteric pain syndrome			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
immune-mediated myositis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
intervertebral disc protrusion			

alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
joint swelling				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
limb discomfort				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
muscle spasms				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
myalgia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
neck pain				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
musculoskeletal chest pain				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
osteoarthritis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
osteochondritis				
alternative dictionary used: MedDRA 26.1				

subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
osteopenia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
pain in extremity				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	2 / 47 (4.26%)			
occurrences (all)	2			
osteoporosis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
rhabdomyolysis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
rheumatic disorder				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
sacral pain				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
spinal pain				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
systemic lupus erythematosus				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			

tendonitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Infections and infestations			
acute sinusitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
bacterial vaginosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[10]	1 / 26 (3.85%)		
occurrences (all)	1		
bronchitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
covid-19			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	6 / 47 (12.77%)		
occurrences (all)	6		
cellulitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
conjunctivitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 47 (4.26%)		
occurrences (all)	2		
cystitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
folliculitis			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
fungal infection				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
hand-foot-and-mouth disease				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
gastroenteritis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
helicobacter infection				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
herpes virus infection				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
herpes zoster				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
helicobacter gastritis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
infected bite				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			

influenza				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	2 / 47 (4.26%)			
occurrences (all)	2			
lower respiratory tract infection				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
onychomycosis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
nasopharyngitis				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
oral fungal infection				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
otitis media				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
paronychia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
pharyngitis streptococcal				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
respiratory tract infection viral				
alternative dictionary used: MedDRA 26.1				

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
sinusitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	2		
tooth infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
upper respiratory tract infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 47 (6.38%)		
occurrences (all)	3		
urinary tract infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 47 (6.38%)		
occurrences (all)	4		
viral rhinitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[11]	0 / 26 (0.00%)		
occurrences (all)	0		
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed[12]	1 / 26 (3.85%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	10 / 47 (21.28%)			
occurrences (all)	12			
diabetes mellitus				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
diabetes mellitus inadequate control				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
dyslipidaemia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
glucose tolerance impaired				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
hyperlipidaemia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
hypercholesterolaemia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
hyperglycaemia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
hyperkalaemia				
alternative dictionary used: MedDRA 26.1				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			

hyperuricaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
vitamin d deficiency			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		

Notes:

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at Risk adjusted accordingly.
[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at Risk adjusted accordingly.
[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at Risk adjusted accordingly.
[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at Risk adjusted accordingly.
[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at Risk adjusted accordingly.
[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at Risk adjusted accordingly.
[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at Risk adjusted accordingly.
[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at Risk adjusted accordingly.
[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at Risk adjusted accordingly.
[12] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants at Risk adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 August 2019	-Updated contraceptive information in Inclusion criteria; - Corrected visit window for Schedule of Activities
21 October 2019	- Modified Schedule of Activities; - Added wording to clarify end of study; - Inclusion and Exclusion Criteria were modified; - Explained purpose of stratification to Minimize Bias: Randomization and Blinding; - Updated Concomitant medication, Hyperglycemia rescue medication, vital signs; - Added patient discontinuation criteria based on TEAE and SAE severity and relatedness; - Added information on duration of storage of liver biopsy tissue blocks and slides; - Reduced the time for follow up liver testing; -Corrected blood glucose values; - Clarified the interim analyses; -Outlined safety reviews based on Lilly Standard Operating Procedures (SOPs); - Added study discontinuation criteria based on TEAE and SAE severity and relatedness; - Moved calcitonin to special laboratory tests; -Added text on additional liver tests
15 November 2019	- Overall Design, primary efficacy assessment, baseline liver biopsy changed from 3 to 6 months; -Inclusion Criteria, Liver Safety: Actions and Follow- Up assessments, Supporting documentation and operational considerations were modified
19 November 2020	- Schedule of Activities and Inclusion criteria were modified; - Added description of the FibroScan-(aspartate aminotransferase [AST]) (FAST) score; -Populations for analyses were modified; - Replaced full analysis set (FAS) with safety analysis set (SS) in safety analyses; - Added procedures in provisions for changes in study conduct during exceptional circumstances

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported