Clinical trial results:
A Phase 2, Double-Blind, Placebo-Controlled Trial to Evaluate the Safety and Efficacy of LY2409021 Compared to Sitagliptin in Subjects with Type 2
Diabetes Mellitus

Summary

EudraCT number	2013-004275-12
Trial protocol	GR
Global end of trial date	28 September 2015

Results information

Result version number	v1 (current)
This version publication date	15 April 2018
First version publication date	15 April 2018

Trial information

Trial identification

Sponsor protocol code	I1R-MC-GLDJ

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02111096
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 15286

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,
Scientific contact	Available Mon-Fri 9 AM- 5 PM EST, Eli Lilly and Company, 1 877-285-4559,

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	28 September 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 September 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The intent of this study is to assess the safety of LY2409021 in participants with Type 2 diabetes mellitus taking metformin and sulfonylurea as prescribed by their personal physician. The study treatment is expected to last 12 months (52 weeks).

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	10 April 2014
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	Greece: 16
Country: Number of subjects enrolled	Puerto Rico: 26
Country: Number of subjects enrolled	United States: 124
Country: Number of subjects enrolled	Taiwan: 8
Worldwide total number of subjects	174
EEA total number of subjects	16

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)	142

From 65 to 84 years	32
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

No text entered.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	LY2409021

Arm description:

20 milligrams (mg) LY2409021 given orally once daily in the morning for 12 months (52 weeks). Participants remained on stable doses of metformin and sulfonylurea, as prescribed by their personal physician.

Arm type	Experimental
Investigational medicinal product name	LY2409021
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

20 milligrams (mg) LY2409021 given orally once daily in the morning for 12 months (52 weeks). Participants remain on stable doses of metformin and sulfonylurea, as prescribed by their personal physician.

Investigational medicinal product name	Metformin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Metformin administered orally at doses prescribed by physician as background drug.

Investigational medicinal product name	Sulfonylurea
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Sulfonylurea is administered orally as doses prescribed by personal physician.

Arm title	Sitagliptin

Arm description:

100 mg sitagliptin given orally once daily in the morning for 12 months (52 weeks). Participants remained on stable doses of metformin and sulfonylurea, as prescribed by their personal physician.

Arm type	Active comparator

Investigational medicinal product name	Sitagliptin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

100 mg sitagliptin given orally once daily in the morning for 12 months (52 weeks). Participants remain on stable doses of metformin and sulfonylurea, as prescribed by their personal physician

Investigational medicinal product name	Metformin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Metformin administered orally at doses prescribed by physician as background drug.

Investigational medicinal product name	Sulfonylurea
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Sulfonylurea is administered orally as doses prescribed by personal physician.

Arm title	Placebo

Arm description:

Placebo matching LY2409021 and sitagliptin given orally once daily in the morning for 12 months (52 weeks). Participants remained on stable doses of metformin and sulfonylurea, as prescribed by their personal physician.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo matching LY2409021 and sitagliptin given orally once daily in the morning for 12 months (52 weeks). Participants remain on stable doses of metformin and sulfonylurea, as prescribed by their personal physician.

Investigational medicinal product name	Metformin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Metformin administered orally at doses prescribed by physician as background drug.

Investigational medicinal product name	Sulfonylurea
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Sulfonylurea is administered orally as doses prescribed by personal physician.

Number of subjects in period 1	LY2409021	Sitagliptin	Placebo
Started	65	41	68
Received at Least 1 Dose of Study Drug	65	41	68
Completed	1	0	2
Not completed	64	41	66
Lost to Follow Up	1	1	1
Terminated by Sponsor	53	35	54
Consent withdrawn by subject	4	2	8
Physician decision	-	1	-
Non-Compliance with Study Drug	1	1	-
Adverse event, non-fatal	4	1	2
Protocol deviation	1	-	1

Baseline characteristics

Reporting groups	
Reporting group title	LY2409021
Reporting group description:	
20 milligrams (mg) LY2409021 given orally once daily in the morning for 12 months (52 weeks). Participants remained on stable doses of metformin and sulfonylurea, as prescribed by their personal physician.	
Reporting group title	Sitagliptin
Reporting group description:	
100 mg sitagliptin given orally once daily in the morning for 12 months (52 weeks). Participants remained on stable doses of metformin and sulfonylurea, as prescribed by their personal physician.	
Reporting group title	Placebo
Reporting group description:	
Placebo matching LY2409021 and sitagliptin given orally once daily in the morning for 12 months (52 weeks). Participants remained on stable doses of metformin and sulfonylurea, as prescribed by their personal physician.	

Reporting group values	LY2409021	Sitagliptin	Placebo
Number of subjects	65	41	68
Age categorical 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)	54	33	55
From 65-84 years	11	8	13
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	56.9	57.1	57.8
standard deviation	± 8.33	± 8.99	± 8.21
Gender, Male/Female Units: Participants			
Female	24	10	31
Male	41	31	37
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	30	19	42
Not Hispanic or Latino	34	21	25
Unknown or Not Reported	1	1	1
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	4	2	5

Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	14	6	11
White	42	31	51
More than one race	5	2	1
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
Greece	6	4	6
Puerto Rico	8	5	13
United States	48	31	45
Taiwan	3	1	4

Reporting group values	Total		
Number of subjects	174		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	142		
From 65-84 years	32		
85 years and over	0		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female Units: Participants			
Female	65		
Male	109		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	91		
Not Hispanic or Latino	80		
Unknown or Not Reported	3		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	11		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	31		
White	124		
More than one race	8		
Unknown or Not Reported	0		
Region of Enrollment Units: Subjects			

Greece	16		
Puerto Rico	26		
United States	124		
Taiwan	8		

End points

End points reporting groups

Reporting group title	LY2409021
Reporting group description:	
20 milligrams (mg) LY2409021 given orally once daily in the morning for 12 months (52 weeks). Participants remained on stable doses of metformin and sulfonylurea, as prescribed by their personal physician.	
Reporting group title	Sitagliptin
Reporting group description:	
100 mg sitagliptin given orally once daily in the morning for 12 months (52 weeks). Participants remained on stable doses of metformin and sulfonylurea, as prescribed by their personal physician.	
Reporting group title	Placebo
Reporting group description:	
Placebo matching LY2409021 and sitagliptin given orally once daily in the morning for 12 months (52 weeks). Participants remained on stable doses of metformin and sulfonylurea, as prescribed by their personal physician.	

Primary: Change from Baseline to 6 Months in Hepatic Fat Fraction

End point title	Change from Baseline to 6 Months in Hepatic Fat Fraction
End point description:	
The hepatic fat fraction (HFF) was calculated by a core imaging laboratory from noncontrast magnetic resonance imaging (MRI) of the liver. Least Squares (LS) means were calculated using mixed model repeated measures (MMRM) adjusting for treatment, country, baseline hemoglobin A1c (HbA1c) stratum (<=8.0%, >8.0%), visit, baseline score, and treatment-by-visit.	
End point type	Primary
End point timeframe:	
Baseline, 6 months	

End point values	LY2409021	Sitagliptin	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62[1]	30[2]	67[3]	
Units: percentage				
least squares mean (confidence interval 95%)	3.65 (2.13 to 5.17)	-0.07 (-1.94 to 1.79)	-0.79 (-2.28 to 0.70)	

Notes:

[1] - Participants who received 1 dose of study drug, MRI HFF baseline and 1 post-baseline data.

[2] - Participants who received 1 dose of study drug, MRI HFF baseline and 1 post-baseline data.

[3] - Participants who received 1 dose of study drug, MRI HFF baseline and 1 post-baseline data.

Statistical analyses

Statistical analysis title	Statistical Analysis for Hepatic Fat Fraction
Comparison groups	Placebo v LY2409021

Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	ANCOVA
Confidence interval	
sides	2-sided
lower limit	1.11
upper limit	3.4

Secondary: Change from Baseline to 6 Months in Alanine Aminotransferase Levels

End point title	Change from Baseline to 6 Months in Alanine Aminotransferase Levels

End point description:

Alanine aminotransferase (ALT) assessed by a central laboratory. Least Squares (LS) means were calculated using mixed model repeated measures (MMRM) adjusting for treatment, country, baseline HbA1c stratum (<=8.0%, >8.0%), visit, baseline score, and treatment-by-visit.

End point type	Secondary

End point timeframe:

Baseline, 6 months

End point values	LY2409021	Sitagliptin	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64[4]	39[5]	67[6]	
Units: microgram per Liter (µ/L)				
least squares mean (confidence interval 95%)	9.4 (4.6 to 14.2)	2.6 (-3.1 to 8.3)	-1.3 (-6.0 to 3.4)	

Notes:

[4] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

[5] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

[6] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of Hepatobiliary Adverse Events of Special Interest (AESI)

End point title	Frequency of Hepatobiliary Adverse Events of Special Interest (AESI)

End point description:

Number of participants with alanine aminotransferase (ALT) or aspartate aminotransferase (AST) greater than 3 times the upper limit of normal at a post-baseline visit. A summary of other non-serious serious adverse events, (AEs, and all SAE 's), regardless of causality, is located in the Reported Adverse Events section.

End point type	Secondary

End point timeframe:

Baseline, 6 months

End point values	LY2409021	Sitagliptin	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65[7]	41[8]	68[9]	
Units: participants				
number (not applicable)	0	1	1	

Notes:

[7] - All randomized participants who received at least 1 dose of study drug.

[8] - All randomized participants who received at least 1 dose of study drug.

[9] - All randomized participants who received at least 1 dose of study drug.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to 6 Months in Fasting Lipids Levels

End point title	Change from Baseline to 6 Months in Fasting Lipids Levels

End point description:

Lipid values (cholesterol, high density lipid (HDL) cholesterol, low density lipid (LDL) cholesterol, and triglycerides) assessed by a central laboratory. Least Squares (LS) means were calculated using mixed model repeated measures (MMRM) adjusting for treatment, country, baseline HbA1c stratum (<=8.0%, >8.0%), visit, baseline score, and treatment-by-visit.

End point type	Secondary

End point timeframe:

Baseline, 6 months

End point values	LY2409021	Sitagliptin	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65[10]	41[11]	68[12]	
Units: millimole per liter (mmol/L)				
least squares mean (confidence interval 95%)				
Cholesterol (n=58,38,60)	0.468 (0.222 to 0.714)	0.006 (-0.282 to 0.295)	0.130 (-0.110 to 0.371)	
HDL Cholesterol (n=58,38,60)	0.046 (-0.008 to 0.100)	0.032 (-0.031 to 0.095)	-0.021 (-0.032 to 0.074)	
Triglycerides (n=58,38,60)	0.375 (0.087 to 0.644)	0.078 (-0.264 to 0.420)	0.099 (-0.183 to 0.381)	
LDL Cholesterol (n=55,36,57)	0.244 (0.019 to 0.486)	-0.075 (-0.342 to 0.192)	0.019 (-0.200 to 0.239)	

Notes:

[10] - Participants who received 1 dose of study drug and have baseline and 1 post-baseline time point.

[11] - Participants who received 1 dose of study drug and have baseline and 1 post-baseline time point.

[12] - Participants who received 1 dose of study drug and have baseline and 1 post-baseline time point.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to 6 Months in Fasting Blood Glucagon

End point title	Change from Baseline to 6 Months in Fasting Blood Glucagon

End point description:

Glucagon values assessed by a central laboratory. Least Squares (LS) means were calculated using mixed model repeated measures (MMRM) adjusting for treatment, country, baseline HbA1c stratum (<=8.0%, >8.0%), visit, baseline score, and treatment-by-visit.

End point type	Secondary

End point timeframe:

Baseline, 6 months

End point values	LY2409021	Sitagliptin	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65[13]	41[14]	68[15]	
Units: picomole per liter (pmol/L)				
least squares mean (confidence interval 95%)	44.06 (36.36 to 51.76)	3.38 (-5.64 to 12.41)	5.05 (-2.50 to 12.60)	

Notes:

[13] - Participants who received 1 dose of study drug and have baseline and 1 post-baseline time point.

[14] - Participants who received 1 dose of study drug and have baseline and 1 post-baseline time point.

[15] - Participants who received 1 dose of study drug and have baseline and 1 post-baseline time point.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to 6 Months in Body Weight

End point title	Change from Baseline to 6 Months in Body Weight

End point description:

Least Squares (LS) means were calculated using mixed model repeated measures (MMRM) adjusting for treatment, country, baseline HbA1c stratum (<=8.0%, >8.0%), visit, baseline score, and treatment-by-visit.

End point type	Secondary

End point timeframe:

Baseline, 6 months

End point values	LY2409021	Sitagliptin	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64[16]	40[17]	68[18]	
Units: kilograms (kg)				
least squares mean (confidence interval 90%)	0.37 (0.12 to 0.63)	-0.08 (-0.39 to 0.22)	-0.05 (-0.30 to 0.20)	

Notes:

[16] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

[17] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

[18] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to 6 Months in Hemoglobin A1c (HbA1c)

End point title	Change from Baseline to 6 Months in Hemoglobin A1c (HbA1c)

End point description:

HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over prolonged periods of time. Least Squares (LS) means were calculated using mixed model repeated measures (MMRM) adjusting for treatment, country, visit, baseline score, and treatment-by-visit.

End point type	Secondary

End point timeframe:

Baseline, 6 months

End point values	LY2409021	Sitagliptin	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63[19]	40[20]	68[21]	
Units: percent of HbA1c				
least squares mean (confidence interval 95%)	-0.63 (-0.94 to -0.32)	-0.42 (-0.80 to -0.05)	0.14 (-0.15 to 0.45)	

Notes:

[19] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

[20] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

[21] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to 6 Months in Fasting Plasma Glucose

End point title	Change from Baseline to 6 Months in Fasting Plasma Glucose

End point description:

Least Squares (LS) means were calculated using mixed model repeated measures (MMRM) adjusting for treatment, country, baseline HbA1c stratum (<=8.0%, >8.0%), visit, baseline score, and treatment-by-visit.

End point type	Secondary

End point timeframe:

Baseline, 6 months

End point values	LY2409021	Sitagliptin	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65[22]	41[23]	68[24]	
Units: milligram per deciliter (mg/dL)				
least squares mean (confidence interval 95%)	-20.5 (-34.3 to -6.6)	-9.4 (-26.3 to 7.4)	6.6 (-7.0 to 20.2)	

Notes:

[22] - Participants who received 1 dose of study drug and have baseline and 1 post-baseline time point.

[23] - Participants who received 1 dose of study drug and have baseline and 1 post-baseline time point.

[24] - Participants who received 1 dose of study drug and have baseline and 1 post-baseline time point.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to 6 Months in Blood Pressure

End point title	Change from Baseline to 6 Months in Blood Pressure

End point description:

Seated systolic blood pressure (SBP) and seated diastolic blood pressure (DBP) were measured in triplicate throughout the study. At each visit, all available blood pressure measurements for a subject were averaged to provide the blood pressure for that visit. Least Squares (LS) means were calculated using mixed model repeated measures (MMRM) adjusting for treatment, country, baseline HbA1c stratum (<=8.0%, >8.0%), visit, baseline score, and treatment-by-visit.

End point type	Secondary

End point timeframe:

Baseline, 6 months

End point values	LY2409021	Sitagliptin	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63[25]	40[26]	68[27]	
Units: millimeters of mercury (mm/Hg)				
least squares mean (confidence interval 95%)				
Systolic Blood Pressure	6.1 (2.7 to 9.5)	1.1 (-2.9 to 5.2)	1.8 (-1.5 to 5.1)	
Diastolic Blood Pressure	2.9 (0.7 to 5.0)	0.3 (-2.3 to 2.9)	1.5 (-0.6 to 3.6)	

Notes:

[25] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

[26] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

[27] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to 6 Months in Pulse Rate

End point title	Change from Baseline to 6 Months in Pulse Rate

End point description:

Seated pulse rate was measured in triplicate throughout the study. At each visit, all available pulse measurements for a subject were averaged to provide the pulse for that visit. Least Squares (LS) means were calculated using mixed model repeated measures (MMRM) adjusting for treatment, country, baseline HbA1c stratum (<=8.0%, >8.0%), visit, baseline score, and treatment-by-visit.

End point type	Secondary

End point timeframe:

Baseline, 6 months

End point values	LY2409021	Sitagliptin	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63[28]	40[29]	68[30]	
Units: beats per minutes (bpm)				
least squares mean (confidence interval 95%)	1.5 (-0.6 to 3.7)	3.5 (0.9 to 6.0)	1.2 (-0.9 to 3.3)	

Notes:

[28] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

[29] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

[30] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to 6 Months in 7-Point Self-Monitoring of Blood Glucose (SMBG)

End point title	Change from Baseline to 6 Months in 7-Point Self-Monitoring of Blood Glucose (SMBG)

End point description:

7-point profile consists of pre-meal and 2-hour postprandial SMBG measurements for the morning, midday, and evening meals in 1 day and at 3 AM (nocturnal blood glucose measurement). Pre-meal measurements were taken before the subject began eating the meal. Participants recorded their glucose measurements in their study diaries.

End point type	Secondary

End point timeframe:

Baseline, 6 months

End point values	LY2409021	Sitagliptin	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65[31]	41[32]	68[33]	
Units: mg/dL				
arithmetic mean (standard deviation)				
Morning Pre-Meal (n=52,28,48)	-29.4 (± 40.36)	-8.13 (± 31.25)	-4.31 (± 26.69)	
Mid-day Pre Meal (n=51,28,47)	-28.43 (± 41.13)	-30.58 (± 48.98)	-9.30 (± 51.08)	
Morning 2 Hour (Hr) Post Meal (n=48,28,44)	-38.8 (± 47.71)	-30.76 (± 44.35)	-18.28 (± 46.20)	
Midday 2 hr Post Meal (n=47,28,45)	-24.22 (± 52.64)	-25.20 (± 61.57)	-10.49 (± 54.17)	
Evening Pre Meal (n=51,28,47)	-24.58 (± 50.78)	-16.78 (± 51.09)	-14.13 (± 50.01)	
Evening 2 hr Post Meal (n=50,28,46)	-28.36 (± 58.92)	-21.12 (± 48.19)	-9.50 (± 48.62)	
Three AM (n=48,27,45)	-22.78 (± 42.49)	-20.12 (± 57.39)	0.88 (± 41.94)	

Notes:

[31] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

[32] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

[33] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

Statistical analyses

No statistical analyses for this end point

Secondary: Population Pharmacokinetics: Apparent Clearance of LY2409021

End point title	Population Pharmacokinetics: Apparent Clearance of LY2409021[34]

End point description:

Reported as a Population Estimate with % Standard Errors of Estimation (SEE), 5th-95th confidence interval.

End point type	Secondary

End point timeframe:

Day 1 Month 1, 3, 6, 9, predose, 1 hour postdose,

Notes:

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint is only measuring for LY2409021 so only that arm is presented.

End point values	LY2409021			
Subject group type	Reporting group			
Number of subjects analysed	65[35]			
Units: Liters per hour (L/h)				
number (confidence interval 95%)	0.526 (0.454 to 0.598)			

Notes:

[35] - All randomized participants who received at least 1 dose of study drug and had evaluable PK data.

Statistical analyses

No statistical analyses for this end point

Secondary: Population Pharmacokinetics: Apparent Volume of Distribution of LY2409021

End point title	Population Pharmacokinetics: Apparent Volume of Distribution of LY2409021[36]

End point description:

End point type	Secondary

End point timeframe:

Day 1 Month 1, 3, 6, 9, predose, 1 hour postdose,

Notes:

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint is only measuring for LY2409021 so only that arm is presented.

End point values	LY2409021			
Subject group type	Reporting group			
Number of subjects analysed	65[37]			
Units: Liters (L)				
number (confidence interval 95%)	31.9 (24.5 to 39.3)			

Notes:

[37] - All randomized participants who received at least 1 dose of study drug and had evaluable PK data.

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of Hypoglycemic Events Adjusted per 30 Days

End point title	Rate of Hypoglycemic Events Adjusted per 30 Days

End point description:

Documented symptomatic hypoglycemia, an event during which typical symptoms of hypoglycemia are accompanied by a measured plasma glucose concentration <=70 mg/dL (<=39 mmol/L),is presented. Rate: (30 days) is calculated as: (number of episodes during the time period divided by the number of days during the time period) multiplied by 30.

End point type	Secondary

End point timeframe:

Baseline through 6 months

End point values	LY2409021	Sitagliptin	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	40	68	
Units: number of episodes per day				
number (not applicable)	0.27	0.19	0.12	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Hypoglycemic Events

End point title	Number of Participants with Hypoglycemic Events

End point description:

Documented symptomatic hypoglycemia, an event during which typical symptoms of hypoglycemia are accompanied by a measured plasma glucose concentration <=70 mg/dL (<=39 mmol/L), is presented. The number of subjects with an event are subjects who had at least one episode of documented symptomatic hypoglycemia during the time period.

End point type	Secondary

End point timeframe:

Baseline through 6 months

End point values	LY2409021	Sitagliptin	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64[38]	40[39]	68[40]	
Units: participants				
number (not applicable)	20	40	68	

Notes:

[38] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

[39] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

[40] - Randomized participants, 1 dose of study drug and evaluable data at baseline and 1 postbaseline.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Entire Study	
Adverse event reporting additional description:	
I1R-MC-GLDJ	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	18.1

Reporting groups	
Reporting group title	LY2409021 20mg
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Sitagliptin 100mg
Reporting group description: -	

Serious adverse events	LY2409021 20mg	Placebo	Sitagliptin 100mg
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 65 (7.69%)	1 / 68 (1.47%)	5 / 41 (12.20%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
renal cell carcinoma			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	1 / 65 (1.54%)	0 / 68 (0.00%)	0 / 41 (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
Injury, poisoning and procedural complications			
femur fracture			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint dislocation			
alternative dictionary used: MedDRA 18.1			

subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
hypertensive crisis			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	1 / 65 (1.54%)	0 / 68 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant hypertension			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure congestive			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ventricular extrasystoles			
alternative dictionary used: MedDRA 18.1			

subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
small intestinal obstruction			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	1 / 68 (1.47%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	1 / 65 (1.54%)	0 / 68 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related infection			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	1 / 65 (1.54%)	0 / 68 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	1 / 65 (1.54%)	0 / 68 (0.00%)	0 / 41 (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
infectious colitis			
alternative dictionary used: MedDRA 18.1			

subjects affected / exposed	1 / 65 (1.54%)	0 / 68 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	1 / 65 (1.54%)	0 / 68 (0.00%)	0 / 41 (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

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	LY2409021 20mg	Placebo	Sitagliptin 100mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 65 (40.00%)	21 / 68 (30.88%)	22 / 41 (53.66%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
colon adenoma			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	2 / 65 (3.08%)	3 / 68 (4.41%)	1 / 41 (2.44%)
occurrences (all)	2	3	1
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
fatigue			

alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	2 / 65 (3.08%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	2	0	1
oedema peripheral			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	2 / 41 (4.88%)
occurrences (all)	0	0	3
pain			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
polyp			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	2 / 68 (2.94%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
pyrexia			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Immune system disorders			
allergy to vaccine			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
seasonal allergy			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
atrophic vulvovaginitis			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			

epistaxis			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	1 / 68 (1.47%)	1 / 41 (2.44%)
occurrences (all)	0	1	1
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
blood pressure diastolic increased			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	2 / 65 (3.08%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	2	0	1
free fatty acids increased			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	2 / 65 (3.08%)	1 / 68 (1.47%)	1 / 41 (2.44%)
occurrences (all)	2	1	1
glomerular filtration rate decreased			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	1 / 65 (1.54%)	2 / 68 (2.94%)	1 / 41 (2.44%)
occurrences (all)	1	2	1
heart rate increased			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	2 / 41 (4.88%)
occurrences (all)	0	0	2
weight decreased			

alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	2 / 65 (3.08%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	2	0	1
weight increased			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	1 / 65 (1.54%)	1 / 68 (1.47%)	1 / 41 (2.44%)
occurrences (all)	1	1	1
Congenital, familial and genetic disorders			
type v hyperlipidaemia			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	1 / 65 (1.54%)	2 / 68 (2.94%)	0 / 41 (0.00%)
occurrences (all)	1	2	0
Cardiac disorders			
coronary artery disease			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
sinus bradycardia			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
ventricular extrasystoles			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Nervous system disorders			
carotid arteriosclerosis			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
dizziness			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	4 / 65 (6.15%)	0 / 68 (0.00%)	0 / 41 (0.00%)
occurrences (all)	5	0	0
headache			

alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	6 / 65 (9.23%)	1 / 68 (1.47%)	2 / 41 (4.88%)
occurrences (all)	8	1	8
tension headache			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	1 / 65 (1.54%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
Ear and labyrinth disorders			
cerumen impaction			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Eye disorders			
blindness unilateral			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
diabetic retinal oedema			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
eye swelling			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
glaucoma			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Gastrointestinal disorders			

abdominal pain			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	1 / 65 (1.54%)	1 / 68 (1.47%)	1 / 41 (2.44%)
occurrences (all)	1	1	1
constipation			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	2 / 65 (3.08%)	0 / 68 (0.00%)	3 / 41 (7.32%)
occurrences (all)	2	0	3
diarrhoea			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	3 / 65 (4.62%)	3 / 68 (4.41%)	1 / 41 (2.44%)
occurrences (all)	3	5	1
dry mouth			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
toothache			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	1 / 65 (1.54%)	2 / 68 (2.94%)	0 / 41 (0.00%)
occurrences (all)	1	2	0
Hepatobiliary disorders			
hepatic cyst			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
pruritus			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
rash			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Renal and urinary disorders			

microalbuminuria			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
nephrolithiasis			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	2 / 65 (3.08%)	1 / 68 (1.47%)	0 / 41 (0.00%)
occurrences (all)	2	2	0
arthritis			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
back pain			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	1 / 65 (1.54%)	1 / 68 (1.47%)	1 / 41 (2.44%)
occurrences (all)	1	1	1
intervertebral disc degeneration			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
musculoskeletal pain			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	2 / 65 (3.08%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	2	0	1
musculoskeletal stiffness			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
myalgia			
alternative dictionary used:			

MedDRA 18.1			
subjects affected / exposed	2 / 65 (3.08%)	0 / 68 (0.00%)	2 / 41 (4.88%)
occurrences (all)	2	0	3
pain in extremity			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	2 / 65 (3.08%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	2	0	1
tendonitis			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	1 / 65 (1.54%)	0 / 68 (0.00%)	3 / 41 (7.32%)
occurrences (all)	1	0	3
conjunctivitis			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
influenza			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	2 / 65 (3.08%)	1 / 68 (1.47%)	2 / 41 (4.88%)
occurrences (all)	2	1	2
labyrinthitis			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
nasopharyngitis			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	2 / 65 (3.08%)	1 / 68 (1.47%)	2 / 41 (4.88%)
occurrences (all)	3	1	3
pharyngitis			
alternative dictionary used: MedDRA 18.1			

subjects affected / exposed	1 / 65 (1.54%)	1 / 68 (1.47%)	1 / 41 (2.44%)
occurrences (all)	1	1	1
pharyngitis streptococcal			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
sinusitis			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	2 / 65 (3.08%)	1 / 68 (1.47%)	0 / 41 (0.00%)
occurrences (all)	2	1	0
subcutaneous abscess			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	1 / 68 (1.47%)	1 / 41 (2.44%)
occurrences (all)	0	1	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	4 / 65 (6.15%)	3 / 68 (4.41%)	3 / 41 (7.32%)
occurrences (all)	6	4	3
viral infection			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	2 / 65 (3.08%)	0 / 68 (0.00%)	0 / 41 (0.00%)
occurrences (all)	4	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	0 / 65 (0.00%)	0 / 68 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
abnormal weight gain			
alternative dictionary used: MedDRA 18.1			
subjects affected / exposed	2 / 65 (3.08%)	0 / 68 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 18.1			

subjects affected / exposed occurrences (all)	0 / 65 (0.00%) 0	0 / 68 (0.00%) 0	1 / 41 (2.44%) 1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Terminated, The overall benefit-risk profile did not support continued development of LY2409021 for type 2 diabetes.

Notes: