Trial record **1 of 1** for: ioqe

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Comparison of the Efficacy and Safety of Two Insulin Intensification Strategies

ClinicalTrials.gov Identifier: NCT01175824

Recruitment Status : Completed
First Posted : August 5, 2010
Results First Posted : February 24, 2014
Last Update Posted : February 24, 2014

Sponsor:
Eli Lilly and Company

Information provided by (Responsible Party):
Eli Lilly and Company

Study Details | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Study Type	Interventional
Study Design	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Condition	Diabetes Mellitus, Type 2
Interventions	Drug: Insulin Lispro Low Mixture (LM) Drug: Insulin Glargine Drug: Prandial Insulin Lispro
Enrollment	478

Participant Flow

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Recruitment Details	
Pre-assignment Details	

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro
Arm/Group Description	Two daily injections (breakfast and dinner) of insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	Once-daily injection (bedtime) basal insulin glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.
Period Title: **Overall Study**		
Started	236	242
Received at Least 1 Dose of Study Drug	236	240
Completed	220	220
Not Completed	16	22

Reason Not Completed		
Adverse Event	2	1
Lack of Efficacy	2	0
Lost to Follow-up	0	1
Physician Decision	0	4
Protocol Violation	2	5
Withdrawal by Subject	3	7
Sponsor Decision	1	0
Entry Criteria Not Met	6	4

Baseline Characteristics

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Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro	Total
Arm/Group Description	Two daily injections (breakfast and dinner) of insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	Once-daily injection (bedtime) basal insulin glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.	Total of all reporting groups
Overall Number of Baseline Participants	236	240	476
Baseline Analysis Population Description	Intent-to-treat population: randomized participants who received at least 1 dose of study drug. Participants were		

		analyzed per the assigned treatment arm regardless of the treatment they actually received.		
Age, Continuous Mean (Standard Deviation) Unit of measure: Years				
	Number Analyzed	236 participants	240 participants	476 participants
		57.4 (9.93)	57.7 (9.12)	57.5 (9.52)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants				
	Number Analyzed	236 participants	240 participants	476 participants
	Female	120 50.8%	142 59.2%	262 55.0%
	Male	116 49.2%	98 40.8%	214 45.0%
Race/Ethnicity, Customized Measure Type: Number Unit of measure: Participants	Number Analyzed	236 participants	240 participants	476 participants
American Indian or Alaska Native		15	17	32

Asian		80	80	160
Native Hawaiian or Other Pacific Islander		0	0	0
Black or African American		5	1	6
White		133	136	269
More than one race		3	6	9
Unknown or Not Reported		0	0	0
Region of Enrollment Measure Type: Number Unit of measure: Participants	Number Analyzed	236 participants	240 participants	476 participants
Argentina		40	39	79
Brazil		20	23	43
China		15	13	28
Egypt		5	7	12
India		40	41	81
Korea, Republic of		25	26	51
Mexico		20	20	40
Romania		38	38	76
Russian Federation		2	3	5
Spain		23	23	46
Turkey		8	7	15

Outcome Measures

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1. Primary Outcome

Title	Change in HbA1c From Baseline to 24 Weeks Endpoint (Per Protocol Population)
Description	The change from baseline to 24 weeks in the percentage of glycosylated hemoglobin A1c (HbA1c) in plasma. The least squares (LS) mean was estimated from a mixed-effects model with repeated measures (MMRM) that included baseline HbA1c concentration as a covariate, treatment, country, week of visit, and treatment-by-week interaction as fixed effects, and participant and error as random effects.
Time Frame	Baseline, 24 weeks

Outcome Measure Data

Analysis Population Description

Per protocol population: randomized participants with the exception of participants who did not complete Week 24 visit, received study drug different from their randomized study treatment, violated any of the inclusion, exclusion, or discontinuation criteria, or were significantly noncompliant.

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro
Arm/Group Description:	Two daily injections (breakfast and dinner) of insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	Once-daily injection (bedtime) basal insulin glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.
Overall Number of Participants Analyzed	220	216

Least Squares Mean (95% Confidence Interval) Unit of Measure: percentage of HbA1c		
	-1.30 (-1.44 to -1.16)	-1.09 (-1.24 to -0.95)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Insulin Lispro Low Mixture, Insulin Glargine+Insulin Lispro
	Comments	[Not Specified]
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	Non-inferiority will be concluded if the upper limit of the 95% confidence interval (CI) of the difference in the LS mean between the two treatment arms (twice-daily insulin lispro Low Mixture minus the comparator arm) at 24 weeks is <0.4%.
Method of Estimation	Estimation Parameter	LS mean difference
	Estimated Value	-0.21
	Confidence Interval	(2-Sided) 95% -0.38 to -0.04
	Estimation Comments	[Not Specified]

2. Primary Outcome

Title	Change in HbA1c From Baseline to 24 Weeks Endpoint (Intention-to-Treat Population)
▼ Description	

	The change from baseline to 24 weeks in the percentage of glycosylated hemoglobin A1c (HbA1c) in plasma. The least squares (LS) mean was estimated from a mixed-effects model with repeated measures (MMRM) that included baseline HbA1c concentration as a covariate, treatment, country, week of visit, and treatment-by-week interaction as fixed effects, and participant and error as random effects.
Time Frame	Baseline, 24 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
Intention-to-treat population (ITT): randomized participants who received at least 1 dose of study drug and had HbA1c data at 24 weeks. Participants were analyzed per their assigned treatment arm regardless of the treatment they actually received.

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro
▼ Arm/Group Description:	Two daily injections (breakfast and dinner) of insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	Once-daily injection (bedtime) basal insulin glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.
Overall Number of Participants Analyzed	220	220
Least Squares Mean (95% Confidence Interval) Unit of Measure: percentage of HbA1c		
	-1.30	-1.08

	(-1.44 to -1.16)	(-1.22 to -0.94)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Insulin Lispro Low Mixture, Insulin Glargine+Insulin Lispro
	Comments	[Not Specified]
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Method of Estimation	Estimation Parameter	LS mean difference
	Estimated Value	-0.22
	Confidence Interval	(2-Sided) 95% -0.39 to -0.05
	Estimation Comments	[Not Specified]

3. Secondary Outcome

Title	Change in the HbA1c Concentration From Baseline to 12 Weeks Endpoint
▼ Description	The change from baseline to 12 weeks in the percentage of glycosylated hemoglobin A1c (HbA1c) in plasma. The least squares (LS) mean was estimated from a mixed-effects model with repeated measures (MMRM) that included baseline HbA1c concentration as a covariate, treatment, country, week of visit, and treatment-by-week interaction as fixed effects, and participant and error as random effects.
Time Frame	Baseline, 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description

Intention-to-treat population (ITT): randomized participants who received at least 1 dose of study drug and had HbA1c data at the 12 weeks. Participants were analyzed per their assigned treatment arm regardless of the treatment they actually received.

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro

▼ Arm/Group Description:	Two daily injections (breakfast and dinner) of insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	Once-daily injection (bedtime) basal insulin glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.
Overall Number of Participants Analyzed	222	226
Least Squares Mean (95% Confidence Interval) Unit of Measure: percentage of HbA1c		
	-1.12 (-1.26 to -0.98)	-1.01 (-1.15 to -0.87)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Insulin Lispro Low Mixture, Insulin Glargine+Insulin Lispro
	Comments	[Not Specified]
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.1858
	Comments	[Not Specified]
	Method	Mixed Models Analysis
	Comments	[Not Specified]

4. Secondary Outcome

Title	

	Number of Participants Who Achieve a Target HbA1c Concentration of Less Than 7% or Less Than or Equal to 6.5% at 24 Weeks
▼ Description	[Not Specified]
Time Frame	24 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
Intention-to-treat population (ITT): randomized participants who received at least 1 dose of study drug and had HbA1c data at 24 weeks. Participants were analyzed per their assigned treatment arm regardless of the treatment they actually received.

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro
▼ Arm/Group Description:	Two daily injections (breakfast and dinner) of insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	Once-daily injection (bedtime) basal insulin glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.
Overall Number of Participants Analyzed	220	220
Measure Type: Number Unit of Measure: participants		
HbA1c <7%	76	66
HbA1c <=6.5%	36	31

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	

		Insulin Lispro Low Mixture, Insulin Glargine+Insulin Lispro
	Comments	[Not Specified]
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.3588
	Comments	HbA1c concentration <7%
	Method	Fisher Exact
	Comments	[Not Specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Insulin Lispro Low Mixture, Insulin Glargine+Insulin Lispro
	Comments	[Not Specified]
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.5958
	Comments	HbA1c <=6.5%
	Method	Fisher Exact
	Comments	[Not Specified]

5. Secondary Outcome

Title	Change in the Fasting Plasma Glucose Concentration From Baseline to 12 Weeks and 24 Weeks
▼ Description	The least squares (LS) mean was estimated from a mixed-effects model with repeated measures (MMRM) that included baseline fasting plasma glucose value as a covariate, treatment, country, baseline HbA1c stratification level, week of visit, and treatment-by-week interaction as fixed effects, and participant and error as random effects.
Time Frame	Baseline, 12 weeks, and 24 weeks

▼ Outcome Measure Data

▼ Analysis Population Description

Intention-to-treat population (ITT): randomized participants who received at least 1 dose of study drug and had fasting plasma glucose concentration data at the specified time points. Participants were analyzed per their assigned treatment arm regardless of the treatment they actually received.

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro
▼ Arm/Group Description:	Two daily injections (breakfast and dinner) of insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	Once-daily injection (bedtime) basal insulin glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.
Overall Number of Participants Analyzed	222	222
Least Squares Mean (95% Confidence Interval) Unit of Measure: millimoles per liter (mmol/L)		
Change at 12 Weeks (n= 222, 222)	1.04 (0.67 to 1.41)	0.64 (0.27 to 1.00)
Change at 24 Weeks (n=219, 217)	0.89 (0.52 to 1.27)	0.75 (0.38 to 1.12)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Insulin Lispro Low Mixture, Insulin Glargine+Insulin Lispro

	Comments	[Not Specified]
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.0827
	Comments	p-value is for the Week 12 comparison
	Method	Mixed Models Analysis
	Comments	[Not Specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Insulin Lispro Low Mixture, Insulin Glargine+Insulin Lispro
	Comments	[Not Specified]
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.5353
	Comments	p-value is for the Week 24 comparison
	Method	Mixed Models Analysis
	Comments	[Not Specified]

6. Secondary Outcome

Title	7-point Self-Monitored Blood Glucose (SMBG) Profiles at 12 Weeks and 24 Weeks
▼ Description	7-point Self-monitored Blood Glucose (SMBG) Profiles are measures of blood glucose taken 7 times a day at the morning pre-meal, morning 2-hours post-meal, midday pre-meal, midday 2-hours post-meal, evening pre-meal, evening 2-hours post-meal, and 0300 hour [3 am]. Each participant took measures on 3 non-consecutive days and the average was calculated for each of the 7 time points. The mean of the 7-point averages was calculated for all the participants at baseline, Weeks 12 and 24. The least squares (LS) mean was estimated from mixed-effects model with repeated measures that included the baseline value

	of the variable as a covariate, treatment, country, baseline glycosylated hemoglobin A1c (HbA1c)stratification level, week of visit, and treatment-by-week interaction as fixed effects, and participant and error as random effects.
Time Frame	12 weeks, 24 weeks

▼ Outcome Measure Data

▼ Analysis Population Description

Intention-to-treat population (ITT): randomized participants who received at least 1 dose of study drug and had SMBG data at the specified time points. Participants were analyzed per their assigned treatment arm regardless of the treatment they actually received.

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro
▼ Arm/Group Description:	Two daily injections (breakfast and dinner) of insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	Once-daily injection (bedtime) basal insulin glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.
Overall Number of Participants Analyzed	229	235
Least Squares Mean (95% Confidence Interval) Unit of Measure: millimoles per liter (mmol/L)		
pre-morning meal (Week 12) (n=223, 222)	6.87 (6.67 to 7.07)	6.20 (6.01 to 6.40)

2 hour post-morning meal (Week 12) (n=220, 221)	8.82 (8.50 to 9.13)	9.01 (8.70 to 9.33)
pre-midday meal (Week 12) (n=220, 221)	6.96 (6.68 to 7.24)	7.44 (7.17 to 7.72)
2 hours post-midday meal (Week 12) (n=220, 221)	9.46 (9.14 to 9.78)	9.14 (8.83 to 9.45)
pre-evening meal (Week 12) (n=221, 221)	7.98 (7.69 to 8.28)	8.25 (7.96 to 8.54)
2 hours post-evening meal (Week 12) (n=217, 220)	9.15 (8.79 to 9.52)	9.10 (8.74 to 9.46)
3 am - during the night (Week 12) (n=197, 201)	8.21 (7.87 to 8.55)	8.52 (8.19 to 8.86)
pre-morning meal (Week 24) (n=217, 216)	6.60 (6.41 to 6.79)	6.26 (6.07 to 6.45)
2 hours post-morning meal (Week 24) (n=216, 215)	8.52 (8.22 to 8.83)	8.86 (8.56 to 9.16)
pre-midday meal (Week 24) (n=215, 216)	6.82 (6.54 to 7.09)	7.44 (7.17 to 7.71)
2 hours post-midday meal (Week 24) (n=216, 216)	9.08 (8.76 to 9.40)	8.99 (8.68 to 9.30)
pre-evening meal (Week 24) (n=216, 216)	7.70 (7.41 to 7.99)	7.95 (7.66 to 8.24)
	9.11 (8.76 to 9.47)	8.95 (8.60 to 9.30)

2 hours post-evening meal (Week 24) (n=212, 216)		
3 am - during the night (Week 24) (n=198, 195)	8.05 (7.72 to 8.38)	8.26 (7.93 to 8.59)

7. Secondary Outcome

Title	Glycemic Variability From the 7-point Self-Monitored Blood Glucose (SMBG) Profiles at 12 Weeks and 24 Weeks
▼ Description	The 7-point SMBG profile was calculated as the average blood glucose concentration across the 7 pre-specified time points in a day that was then averaged over 3 non-consecutive days in the 2 weeks prior to the 12 week visit and 24 week visit. Glycemic variability was calculated as the standard deviation of the 7-point SMBG profiles. Standard deviation was first calculated for each day and then averaged over 3 non-consecutive days for each visit. The least squares (LS) mean was estimated from mixed-effects model with repeated measures that included the baseline value of the variable as a covariate, treatment, country, baseline glycosylated hemoglobin A1c (HbA1c)stratification level, week of visit, and treatment-by-week interaction as fixed effects, and participant and error as random effects.
Time Frame	12 weeks, 24 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
Intention-to-treat population (ITT): randomized participants who received at least 1 dose of study drug and had SMBG glycemic variability data at the specified time points. Participants were analyzed per their assigned treatment arm regardless of the treatment they actually received.

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro
▼ Arm/Group Description:	Two daily injections (breakfast and dinner) of insulin lispro mix	Once-daily injection (bedtime) basal insulin glargine and

	75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.
Overall Number of Participants Analyzed	220	221
Least Squares Mean (95% Confidence Interval) Unit of Measure: millimoles/liter (mmol/L)		
SMBG glycemic variability, 12 weeks (n=220, 221)	2.12 (2.01 to 2.24)	2.13 (2.01 to 2.24)
SMBG glycemic variability, 24 weeks (n=216, 216)	2.03 (1.92 to 2.14)	1.99 (1.88 to 2.10)

8. Secondary Outcome

Title	Daily Insulin Dose: Total, Basal, and Prandial at 12 Weeks and 24 Weeks
▼ Description	[Not Specified]
Time Frame	12 weeks, 24 weeks

▼ Outcome Measure Data

▼ Analysis Population Description

Intention-to-treat population (ITT): randomized participants who received at least 1 dose of study drug and had dosing data at the specified time points. Participants were analyzed per their assigned treatment arm regardless of the treatment they actually received.

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro
▼ Arm/Group Description:	Two daily injections (breakfast and dinner) of insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	Once-daily injection (bedtime) basal insulin glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.
Overall Number of Participants Analyzed	236	240
Mean (Standard Deviation) Unit of Measure: international units (IU)		
Total Insulin Dose at 12 Weeks (n=224, 224)	51.2 (23.60)	49.2 (20.89)
Total Insulin Dose at 24 Weeks LOCF (n=236, 240)	53.1 (24.60)	50.8 (21.96)
Basal Insulin Dose at 12 Weeks (n=224, 224)	38.4 (17.70)	37.1 (18.34)
Basal Insulin Dose at 24 Weeks LOCF (n=236, 240)	39.8 (18.45)	37.4 (18.76)
Prandial Insulin Dose at 12 Weeks (n=224, 224)	12.8 (5.90)	12.1 (5.10)
	13.3 (6.15)	13.5 (6.46)

Prandial Insulin Dose at 24 Weeks LOCF(n=236, 240)		

9. Secondary Outcome

Title	Change in Weight From Baseline to 12 Weeks and 24 Weeks
▼ Description	The least squares (LS) mean was estimated from a mixed-effects model with repeated measures (MMRM) that included baseline weight as a covariate, treatment, country, baseline glycosylated hemoglobin A1c (HbA1c) stratification level, week of visit, and the treatment-by-week interaction as fixed effects, and participant and error as random effects.
Time Frame	Baseline, 12 weeks, 24 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
Safety population: randomized participants who took at least 1 dose of study drug and had evaluable body weight data at the specified time points.

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro
▼ Arm/Group Description:	Two daily injections (breakfast and dinner) of insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	Once-daily injection (bedtime) basal insulin glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.
Overall Number of Participants Analyzed	224	225

Least Squares Mean (95% Confidence Interval) Unit of Measure: kilograms (kg)		
Change at 12 weeks (n=224, 225)	0.54 (0.25 to 0.83)	0.34 (0.05 to 0.62)
Change at 24 weeks (n=219, 217)	1.13 (0.75 to 1.52)	0.50 (0.11 to 0.89)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Insulin Lispro Low Mixture, Insulin Glargine+Insulin Lispro
	Comments	[Not Specified]
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.2833
	Comments	p-value is for the comparison at Week 12.
	Method	Mixed Models Analysis
	Comments	[Not Specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Insulin Lispro Low Mixture, Insulin Glargine+Insulin Lispro
	Comments	[Not Specified]
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.0176
	Comments	p-value is for the comparison at Week 24.
	Method	Mixed Models Analysis
	Comments	[Not Specified]

10. Secondary Outcome

Title	The Number of Participants With a Hypoglycemic Episodes (Incidence)
▼ Description	A hypoglycemic episode was defined as an event associated with 1) reported signs and symptoms of hypoglycemia, and/or 2) a documented blood glucose (BG) concentration of <= 70 milligrams per deciliter [mg/dL, 3.9 millimoles per liter (mmol/L)].
Time Frame	Baseline through 24 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
Safety population: randomized participants who took at least 1 dose of study drug.

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro
▼ Arm/Group Description:	Two daily injections (breakfast and dinner) of insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	Once-daily injection (bedtime) basal insulin glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.
Overall Number of Participants Analyzed	236	240
Measure Type: Number Unit of Measure: participants		
	144	150

11. Secondary Outcome

Title	Insulin Treatment Satisfaction Questionnaire (ITSQ) Score at 24 Weeks
▼ Description	ITSQ: validated instrument containing 22 items which are measured on a 7-point scale: 1 (no bother at all) to 7 (a tremendous bother) used to assess insulin treatment satisfaction. Items are divided into 5 domains: Inconvenience of Regimen (5 items: domain score range 5 to 35), Lifestyle Flexibility (3 items: domain score range 3 to 21), Glycemic Control (3 items: domain score range 3 to 21), Hypoglycemic Control (5 items: domain score range 5 to 35), Insulin Delivery Device (6 items: domain score range 6 to 42) lower scores reflect better outcome. ITSQ Total Overall Score ranged from 22 to 154. Raw domain scores transformed on 0-100 scale, where transformed domain score = 100×[(7-raw domain score)/6]. Higher scores indicate better treatment satisfaction. Least squares (LS) mean estimated from analysis of covariance (ANCOVA) model that included baseline score as covariate and treatment, glycosylated hemoglobin A1c (HbA1c) stratum, and country as fixed effects.
Time Frame	24 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
Randomized participants who received at least 1 dose of study drug and had ITSQ scores at 24 weeks. Last observation carried forward (LOCF).

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro
▼ Arm/Group Description:	Two daily injections (breakfast and dinner) of insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	Once-daily injection (bedtime) basal insulin glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses,

		administered subcutaneously for 24 weeks.
Overall Number of Participants Analyzed	230	229
Least Squares Mean (95% Confidence Interval) Unit of Measure: units on a scale		
	80.91 (79.02 to 82.81)	81.84 (79.97 to 83.72)

12. Secondary Outcome

Title	Perceptions About Medications-Diabetes 21 (PAM-D21) Questionnaire Score at 24 Weeks
▼ Description	PAM-D21 is a validated questionnaire consisting of 21 items to assess a participant's perceptions about their diabetes treatment regimens and perceived emotional and physical side-effects. The PAM-D21 consists of 4 subscales: Convenience/Flexibility (items 1 to 3); Perceived Effectiveness (items 4 to 6); Emotional Effects (items 7 to 11); and Physical Effects (items 12 to 21). Item scores range from 1 (none of the time) to 4 (all of the time). Subscale scores were linearly transformed to a 0-100, with higher score corresponds to better perceptions about diabetes medications. The least squares (LS) mean was estimated from an analysis of covariance (ANCOVA) model that included baseline score as a covariate and treatment, glycosylated hemoglobin A1c (HbA1c) stratum, and country as fixed effects.
Time Frame	24 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
Randomized participants who received at least 1 dose of study drug and had PAM-D21 scores at 24 weeks.

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro
▼ Arm/Group Description:	Two daily injections (breakfast and dinner) of insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	Once-daily injection (bedtime) basal insulin glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.
Overall Number of Participants Analyzed	231	230
Least Squares Mean (95% Confidence Interval) Unit of Measure: units on a scale		
Convenience/Flexibility (n= 231, 230)	83.90 (81.00 to 86.80)	84.13 (81.26 to 87.00)
Perceived Effectiveness (n=231, 230)	76.78 (73.32 to 80.23)	78.76 (75.34 to 82.17)
Emotional Effects (n=231, 230)	81.84 (78.87 to 84.80)	81.86 (78.92 to 84.79)
Physical Effects (n=231, 228)	87.89 (86.20 to 89.58)	89.04 (87.37 to 90.72)

13. Secondary Outcome

Title	The Rate of Hypoglycemic Episodes
▼ Description	The hypoglycemia rate per 30 days was calculated as the number of episodes reported for the interval between visits and during the study divided by the number of days in the given interval and multiplied by 30.
Time Frame	Baseline through 24 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
Safety population: randomized participants who took at least 1 dose of study drug.

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro
▼ Arm/Group Description:	Two daily injections (breakfast and dinner) of insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	Once-daily injection (bedtime) basal insulin glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.
Overall Number of Participants Analyzed	236	240
Mean (Standard Deviation) Unit of Measure: hypoglycemic episodes per 30 day period		
	1.07 (1.181)	1.36 (2.172)

14. Secondary Outcome

Title	The Number of Participants With Severe Hypoglycemic Episodes
▼ Description	The number of participants who had a severe hypoglycemic episode anytime during the study. Severe hypoglycemia was defined as any event in which the participant required the assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions.
Time Frame	Baseline through 24 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
Safety population: randomized participants who took at least 1 dose of study drug.

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro
▼ Arm/Group Description:	Two daily injections (breakfast and dinner) of insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	Once-daily injection (bedtime) basal insulin glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.
Overall Number of Participants Analyzed	236	240
Measure Type: Number Unit of Measure: participants		
	2	0

Adverse Events

Go to ▼

Time Frame	[Not Specified]
Adverse Event Reporting Description	[Not Specified]

Arm/Group Title	Insulin Lispro Low Mixture	Insulin Glargine+Insulin Lispro
▼ Arm/Group Description	Two daily injections (breakfast and dinner) of	Once-daily injection (bedtime) basal insulin

	insulin lispro mix 75/25. Participant-dependent doses, administered subcutaneously for 24 weeks.	glargine and once-daily injection (before the meal with the highest average 2-hour postprandial blood glucose concentration) prandial insulin lispro. Participant-dependent doses, administered subcutaneously for 24 weeks.

All-Cause Mortality

	Insulin Lispro Low Mixture		Insulin Glargine+Insulin Lispro	
	Affected / at Risk (%)		Affected / at Risk (%)	
Total	--/--		--/--	

Serious Adverse Events

	Insulin Lispro Low Mixture		Insulin Glargine+Insulin Lispro	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	11/236 (4.66%)		8/240 (3.33%)	
Cardiac disorders				
Myocardial infarction †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Eye disorders				
Retinal vein occlusion †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Infections and infestations				
Bronchitis †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Epiglottitis †1	1/236 (0.42%)	2	0/240 (0.00%)	0
Laryngitis †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Nasopharyngitis †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Respiratory tract infection †1	1/236 (0.42%)	1	0/240 (0.00%)	0

Injury, poisoning and procedural complications				
Fall [†1]	1/236 (0.42%)	1	0/240 (0.00%)	0
Overdose [†1]	0/236 (0.00%)	0	1/240 (0.42%)	1
Pelvic fracture [†1]	1/236 (0.42%)	1	0/240 (0.00%)	0
Metabolism and nutrition disorders				
Hyperglycaemia [†1]	0/236 (0.00%)	0	1/240 (0.42%)	1
Hypoglycaemia [†1]	3/236 (1.27%)	3	1/240 (0.42%)	1
Musculoskeletal and connective tissue disorders				
Intervertebral disc protrusion [†1]	2/236 (0.85%)	3	0/240 (0.00%)	0
Limb discomfort [†1]	1/236 (0.42%)	1	0/240 (0.00%)	0
Pain in extremity [†1]	1/236 (0.42%)	1	0/240 (0.00%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Benign neoplasm of adrenal gland [†1]	0/236 (0.00%)	0	1/240 (0.42%)	1
Gastric cancer [†1]	1/236 (0.42%)	1	0/240 (0.00%)	0
Nervous system disorders				
Cerebral haemorrhage [†1]	0/236 (0.00%)	0	1/240 (0.42%)	1
Renal and urinary disorders				
Nephrolithiasis [†1]	1/236 (0.42%)	1	0/240 (0.00%)	0
Respiratory, thoracic and mediastinal disorders				
Respiratory failure [†1]	1/236 (0.42%)	1	0/240 (0.00%)	0
Surgical and medical procedures				
Toe amputation [†1]	0/236 (0.00%)	0	1/240 (0.42%)	1

† Indicates events were collected by systematic assessment

1 Term from vocabulary, 15.1

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	0%			
	Insulin Lispro Low Mixture		**Insulin Glargine+Insulin Lispro**	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	109/236 (46.19%)		93/240 (38.75%)	
Blood and lymphatic system disorders				
Anaemia †1	1/236 (0.42%)	1	2/240 (0.83%)	2
Cardiac disorders				
Myocardial ischaemia †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Palpitations †1	2/236 (0.85%)	2	0/240 (0.00%)	0
Congenital, familial and genetic disorders				
Birth mark †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Ear and labyrinth disorders				
Vertigo †1	3/236 (1.27%)	3	1/240 (0.42%)	1
Eye disorders				
Cataract †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Conjunctival hyperaemia †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Conjunctivitis †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Diabetic retinopathy †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Eye pain †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Vision blurred †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Gastrointestinal disorders				
Abdominal discomfort †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Abdominal distension †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Abdominal pain †1	3/236 (1.27%)	3	2/240 (0.83%)	2

Abdominal pain upper †1	0/236 (0.00%)	0	4/240 (1.67%)	4
Apical granuloma †1	1/236 (0.42%)	1	1/240 (0.42%)	1
Constipation †1	2/236 (0.85%)	2	3/240 (1.25%)	3
Dental caries †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Diarrhoea †1	6/236 (2.54%)	6	4/240 (1.67%)	6
Dyspepsia †1	2/236 (0.85%)	2	3/240 (1.25%)	3
Enteritis †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Enterocolitis †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Food poisoning †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Gastric ulcer †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Gastritis †1	0/236 (0.00%)	0	2/240 (0.83%)	2
Gastrointestinal disorder †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Inguinal hernia †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Mouth haemorrhage †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Nausea †1	0/236 (0.00%)	0	4/240 (1.67%)	4
Odynophagia †1	1/236 (0.42%)	1	2/240 (0.83%)	2
Periodontal disease †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Stomatitis †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Tongue oedema †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Toothache †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Vomiting †1	4/236 (1.69%)	4	1/240 (0.42%)	1
General disorders				
Asthenia †1	3/236 (1.27%)	3	1/240 (0.42%)	1
Chest discomfort †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Chest pain †1	1/236 (0.42%)	1	2/240 (0.83%)	2
Discomfort †1	1/236 (0.42%)	1	1/240 (0.42%)	1
Face oedema †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Fatigue †1	0/236 (0.00%)	0	2/240 (0.83%)	4
Influenza like illness †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Injection site haematoma †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Injection site pain †1	0/236 (0.00%)	0	2/240 (0.83%)	2
Oedema †1	0/236 (0.00%)	0	1/240 (0.42%)	1

Oedema peripheral †1	1/236 (0.42%)	1	2/240 (0.83%)	2
Pyrexia †1	3/236 (1.27%)	3	4/240 (1.67%)	4
Hepatobiliary disorders				
Cholecystitis †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Cholelithiasis †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Hepatic steatosis †1	2/236 (0.85%)	2	0/240 (0.00%)	0
Immune system disorders				
Drug hypersensitivity †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Infections and infestations				
Acute tonsillitis †1	2/236 (0.85%)	2	1/240 (0.42%)	1
Bronchitis †1	3/236 (1.27%)	3	0/240 (0.00%)	0
Cystitis †1	1/236 (0.42%)	1	1/240 (0.42%)	1
Dengue fever †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Furuncle †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Gastroenteritis †1	4/236 (1.69%)	4	0/240 (0.00%)	0
Gastroenteritis viral †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Gingivitis †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Herpes zoster †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Influenza †1	3/236 (1.27%)	3	4/240 (1.67%)	4
Keratitis herpetic †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Laryngitis †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Localised infection †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Nasopharyngitis †1	20/236 (8.47%)	24	13/240 (5.42%)	13
Orchitis †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Periodontitis †1	1/236 (0.42%)	1	1/240 (0.42%)	1
Pharyngitis †1	2/236 (0.85%)	2	3/240 (1.25%)	3
Pulpitis dental †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Pyelonephritis acute †1	0/236 (0.00%)	0	1/240 (0.42%)	2
Respiratory tract infection †1	2/236 (0.85%)	3	0/240 (0.00%)	0
Respiratory tract infection viral †1	0/236 (0.00%)	0	2/240 (0.83%)	2
Rhinitis †1	1/236 (0.42%)	1	1/240 (0.42%)	1
Sinusitis †1	1/236 (0.42%)	1	2/240 (0.83%)	2

Tinea pedis †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Tonsillitis †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Tooth abscess †1	3/236 (1.27%)	4	1/240 (0.42%)	1
Tooth infection †1	1/236 (0.42%)	1	1/240 (0.42%)	1
Upper respiratory tract infection †1	2/236 (0.85%)	2	3/240 (1.25%)	3
Urinary tract infection †1	3/236 (1.27%)	4	5/240 (2.08%)	7
Wound infection †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Injury, poisoning and procedural complications				
Arthropod sting †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Burns third degree †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Contusion †1	1/236 (0.42%)	1	1/240 (0.42%)	1
Corneal abrasion †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Excoriation †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Injury †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Joint injury †1	0/236 (0.00%)	0	2/240 (0.83%)	2
Laceration †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Ligament sprain †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Limb injury †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Lower limb fracture †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Meniscus lesion †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Muscle strain †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Spinal column injury †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Tooth fracture †1	1/236 (0.42%)	1	1/240 (0.42%)	1
Wound secretion †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Wrist fracture †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Investigations				
Alanine aminotransferase increased †1	1/236 (0.42%)	1	1/240 (0.42%)	1
Blood creatinine increased †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Blood pressure increased †1	0/236 (0.00%)	0	1/240 (0.42%)	1

Hepatic enzyme increased [†1]	1/236 (0.42%)	1	0/240 (0.00%)	0
Weight increased [†1]	2/236 (0.85%)	2	0/240 (0.00%)	0
Metabolism and nutrition disorders				
Decreased appetite [†1]	1/236 (0.42%)	1	0/240 (0.00%)	0
Dyslipidaemia [†1]	2/236 (0.85%)	2	0/240 (0.00%)	0
Hyperlipidaemia [†1]	1/236 (0.42%)	1	0/240 (0.00%)	0
Hypoalbuminaemia [†1]	0/236 (0.00%)	0	1/240 (0.42%)	1
Hypocalcaemia [†1]	0/236 (0.00%)	0	1/240 (0.42%)	1
Musculoskeletal and connective tissue disorders				
Arthralgia [†1]	6/236 (2.54%)	6	5/240 (2.08%)	5
Back pain [†1]	4/236 (1.69%)	4	6/240 (2.50%)	8
Bursitis [†1]	0/236 (0.00%)	0	1/240 (0.42%)	1
Gouty arthritis [†1]	1/236 (0.42%)	1	0/240 (0.00%)	0
Intervertebral disc protrusion [†1]	0/236 (0.00%)	0	2/240 (0.83%)	2
Joint swelling [†1]	0/236 (0.00%)	0	1/240 (0.42%)	1
Limb discomfort [†1]	0/236 (0.00%)	0	1/240 (0.42%)	1
Muscle spasms [†1]	0/236 (0.00%)	0	1/240 (0.42%)	1
Muscular weakness [†1]	1/236 (0.42%)	1	0/240 (0.00%)	0
Musculoskeletal pain [†1]	0/236 (0.00%)	0	1/240 (0.42%)	1
Neck pain [†1]	2/236 (0.85%)	2	0/240 (0.00%)	0
Osteoarthritis [†1]	0/236 (0.00%)	0	2/240 (0.83%)	2
Osteoporosis [†1]	1/236 (0.42%)	1	0/240 (0.00%)	0
Pain in extremity [†1]	1/236 (0.42%)	1	6/240 (2.50%)	7
Periarthritis [†1]	1/236 (0.42%)	1	0/240 (0.00%)	0
Rheumatic disorder [†1]	1/236 (0.42%)	1	0/240 (0.00%)	0
Synovial cyst [†1]	0/236 (0.00%)	0	1/240 (0.42%)	1
Tendonitis [†1]	0/236 (0.00%)	0	1/240 (0.42%)	1

Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Seborrhoeic keratosis †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Nervous system disorders				
Burning sensation †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Carpal tunnel syndrome †1	2/236 (0.85%)	3	1/240 (0.42%)	1
Diabetic neuropathy †1	0/236 (0.00%)	0	2/240 (0.83%)	2
Dizziness †1	5/236 (2.12%)	6	4/240 (1.67%)	6
Headache †1	7/236 (2.97%)	9	7/240 (2.92%)	7
Hypoaesthesia †1	2/236 (0.85%)	2	0/240 (0.00%)	0
Paraesthesia †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Radiculopathy †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Sciatica †1	0/236 (0.00%)	0	3/240 (1.25%)	3
Tremor †1	1/236 (0.42%)	1	1/240 (0.42%)	1
Psychiatric disorders				
Anxiety †1	2/236 (0.85%)	2	3/240 (1.25%)	3
Insomnia †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Sleep disorder †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Renal and urinary disorders				
Dysuria †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Micturition disorder †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Nephrolithiasis †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Renal colic †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Reproductive system and breast disorders				
Vaginal discharge †1	0/120 (0.00%)	0	1/142 (0.70%)	1
Respiratory, thoracic and mediastinal disorders				
Bronchospasm †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Cough †1	2/236 (0.85%)	3	0/240 (0.00%)	0
Epistaxis †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Nasal congestion †1	1/236 (0.42%)	1	0/240 (0.00%)	0

Oropharyngeal pain †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Productive cough †1	1/236 (0.42%)	2	0/240 (0.00%)	0
Respiratory failure †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Rhinalgia †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Rhinitis allergic †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Rhinorrhoea †1	0/236 (0.00%)	0	2/240 (0.83%)	2
Sinus disorder †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Throat irritation †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Skin and subcutaneous tissue disorders				
Dermatitis allergic †1	1/236 (0.42%)	2	0/240 (0.00%)	0
Dermatitis contact †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Eczema †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Hirsutism †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Hyperhidrosis †1	2/236 (0.85%)	2	2/240 (0.83%)	2
Pityriasis †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Pruritus †1	2/236 (0.85%)	2	2/240 (0.83%)	2
Pruritus generalised †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Rash †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Rash vesicular †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Skin lesion †1	1/236 (0.42%)	1	1/240 (0.42%)	1
Urticaria †1	1/236 (0.42%)	1	1/240 (0.42%)	1
Surgical and medical procedures				
Carpal tunnel decompression †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Cataract operation †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Meniscus operation †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Shoulder operation †1	1/236 (0.42%)	1	0/240 (0.00%)	0
Tooth extraction †1	0/236 (0.00%)	0	2/240 (0.83%)	4
Vascular disorders				
Haematoma †1	0/236 (0.00%)	0	1/240 (0.42%)	1
Hypertension †1	1/236 (0.42%)	2	2/240 (0.83%)	2
Hypertensive crisis †1	1/236 (0.42%)	1	1/240 (0.42%)	1

Vein disorder †1	0/236 (0.00%)	0	1/240 (0.42%)	1

† Indicates events were collected by systematic assessment

1 Term from vocabulary, 15.1

Limitations and Caveats

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[Not Specified]

More Information

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Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact

Name/Title: Chief Medical Officer
Organization: Eli Lilly and Company
Phone: 800-545-5979

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Rojas A, Sposetti G, Gross JL, Barbieri DE, Duan R, Linetzky B, De Lana JM, Stempa O, Rodriguez A. Insulin lispro low mixture twice daily vs basal insulin glargine once daily and prandial insulin lispro once daily as insulin intensification strategies in patients with type 2 diabetes: Latin American subpopulation analysis of a randomized trial. Diabetol Metab Syndr. 2016 Sep 17;8:69. doi: 10.1186/s13098-016-0163-3. eCollection 2016.

Gross JL, Rojas A, Shah S, Tinahones FJ, Cleall S, Rodríguez A. Efficacy and safety of a premixed versus a basal-plus insulin regimen as intensification for type 2 diabetes by timing of the main meal. Curr Med Res Opin. 2016 Jun;32(6):1109-16. doi: 10.1185/03007995.2016.1161609. Epub 2016 Apr 7.

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Responsible Party:	Eli Lilly and Company
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