Trial record **1 of 1** for: F3Z-MC-IOQC

Previous Study | Return to List | Next Study

Study of Insulin Lispro in Participants With Inadequately Controlled Type 2 Diabetes (AUTONOMY)

ClinicalTrials.gov Identifier: NCT01215955

Recruitment Status : Completed
First Posted : October 7, 2010
Results First Posted : February 27, 2014
Last Update Posted : April 23, 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 Drug: Glargine

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Protocol had 2 independent studies (Study A, Study B) from which data was analyzed separately and independently: Participants were randomized to 1of the 2 treatment arms (Q1D, Q3D) at the site level. Sites were assigned to a study according to an allocation plan that was pre-specified before initiation of the study.

Reporting Groups

	Description
Study A Q1D	Insulin lispro administered subcutaneously, up to 3 times daily for 24 weeks. Mealtime bolus of insulin lispro self-titrated dose was based on blood glucose reading from the previous day (Q1D). Glargine participant-dependent doses, administered subcutaneously once daily for 24 weeks. Participants were randomized to Q1D at the site level: sites were assigned to Study A according to an allocation plan that was pre-specified before initiation of Study A.
Study A Q3D	Insulin lispro administered subcutaneously, up to 3 times daily for 24 weeks. Mealtime bolus of insulin lispro self-titrated dose was based on blood glucose readings from the past 3 days (Q3D). Glargine participant-dependent doses, administered subcutaneously once daily for 24 weeks. Participants were randomized to Q3D at the site level: sites were assigned to Study A according to an allocation plan that was pre-specified before initiation of Study A.
Study B Q1D	Insulin lispro administered subcutaneously, up to 3 times daily for 24 weeks. Mealtime bolus of insulin lispro self-titrated dose was based on blood glucose reading from the previous day (Q1D).

	Glargine participant-dependent doses, administered subcutaneously once daily for 24 weeks. Participants were randomized to Q1D at the site level: sites were assigned to Study B according to an allocation plan that was pre-specified before initiation of Study B.
Study B Q3D	Insulin lispro administered subcutaneously, up to 3 times daily for 24 weeks. Mealtime bolus of insulin lispro self-titrated dose was based on blood glucose readings from the past 3 days (Q3D). Glargine participant-dependent doses, administered subcutaneously once daily for 24 weeks. Participants were randomized to Q3D at the site level: sites were assigned to Study B according to an allocation plan that was pre-specified before initiation of Study B.

Participant Flow: Overall Study

	Study A Q1D	Study A Q3D	Study B Q1D	Study B Q3D
STARTED	268	263	292 [1]	294 [2]
Received at Least 1 Dose of Study Drug	267	261	288	290
COMPLETED	223	210	244	241
NOT COMPLETED	45	53	48	53
Adverse Event	1	4	2	3
Death	2	0	1	3
Entry Criteria Not Met	1	3	4	7
Lack of Efficacy	1	2	1	0
Lost to Follow-up	4	4	8	9
Physician Decision	4	10	8	11
Protocol Violation	17	13	8	8
Sponsor Decision	1	2	0	1
Withdrawal by Subject	14	15	13	9
Quality Issues	0	0	3	2

[1] Three (3) participants from 1 site were excluded due to quality issues and validity of data.

[2] Two (2) participants from 1 site were excluded due to quality issues and validity of the data.

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set-all participants who entered this study, completed the lead-in period (if applicable), were randomized and received ≥1 dose of study insulin, except the participants from the site excluded due to quality issues and data validity.

Reporting Groups

	Description
Study A Q1D	Insulin lispro administered subcutaneously, up to 3 times daily for 24 weeks. Mealtime bolus of insulin lispro self-titrated dose was based on blood glucose reading from the previous day (Q1D). Glargine participant-dependent doses, administered subcutaneously once daily for 24 weeks. Participants were randomized to Q1D at the site level: sites were assigned to Study A according to an allocation plan that was pre-specified before initiation of Study A.
Study A Q3D	Insulin lispro administered subcutaneously, up to 3 times daily for 24 weeks. Mealtime bolus of insulin lispro self-titrated based dose was on blood glucose readings from the past 3 days (Q3D). Glargine participant-dependent doses, administered subcutaneously once daily for 24 weeks. Participants were randomized to Q3D at the site level: sites were assigned to Study A according to an allocation plan that was pre-specified before initiation of Study A.
Study B Q1D	Insulin lispro administered subcutaneously, up to 3 times daily for 24 weeks. Mealtime bolus of insulin lispro self-titrated dose was based on blood glucose reading from the previous day (Q1D). Glargine participant-dependent doses, administered subcutaneously once daily for 24 weeks. Participants were randomized to Q1D at the site level: sites were assigned to Study B according to an allocation plan that was pre-specified before initiation of Study B.
Study B Q3D	

	Insulin lispro administered subcutaneously, up to 3 times daily for 24 weeks. Mealtime bolus of insulin lispro self-titrated dose was based on blood glucose readings from the past 3 days (Q3D). Glargine participant-dependent doses, administered subcutaneously once daily for 24 weeks. Participants were randomized to Q3D at the site level: sites were assigned to Study B according to an allocation plan that was pre-specified before initiation of Study B.
Total	Total of all reporting groups

Baseline Measures

	Study A Q1D	Study A Q3D	Study B Q1D	Study B Q3D	Total
Overall Participants Analyzed [Units: Participants]	**267**	**261**	**288**	**290**	**1106**
Age [Units: Years] Mean (Standard Deviation)	**57.89 (10.25)**	**58.82 (9.46)**	**57.71 (9.71)**	**57.01 (10.61)**	**57.83 (10.03)**
Gender [Units: Participants]					
Female	**133**	**138**	**155**	**155**	**581**
Male	**134**	**123**	**133**	**135**	**525**
Ethnicity (NIH/OMB) [Units: Participants]					
Hispanic or Latino	**100**	**96**	**91**	**95**	**382**
Not Hispanic or Latino	**150**	**153**	**182**	**177**	**662**
Unknown or Not Reported	**17**	**12**	**15**	**18**	**62**
Race (NIH/OMB) [Units: Participants]					
American Indian or	**22**	**20**	**11**	**11**	**64**

Alaska Native					
Asian	**4**	**4**	**8**	**2**	**18**
Native Hawaiian or Other Pacific Islander	**0**	**2**	**0**	**0**	**2**
Black or African American	**20**	**15**	**35**	**29**	**99**
White	**219**	**218**	**228**	**240**	**905**
More than one race	**1**	**2**	**4**	**6**	**13**
Unknown or Not Reported	**1**	**0**	**2**	**2**	**5**
Region of Enrollment [Units: Participants]					
Argentina	**28**	**28**	**37**	**38**	**131**
Austria	**0**	**1**	**4**	**1**	**6**
Brazil	**2**	**4**	**11**	**14**	**31**
Canada	**5**	**6**	**7**	**11**	**29**
Croatia	**3**	**3**	**4**	**5**	**15**
Denmark	**5**	**0**	**1**	**0**	**6**
France	**3**	**0**	**1**	**3**	**7**
Lithuania	**2**	**4**	**4**	**5**	**15**
Mexico	**31**	**31**	**21**	**25**	**108**
Poland	**9**	**8**	**15**	**15**	**47**
Puerto Rico	**26**	**19**	**7**	**7**	**59**
Romania	**9**	**6**	**11**	**10**	**36**
Russian Federation	**12**	**13**	**15**	**16**	**56**
South Africa	**1**	**2**	**11**	**13**	**27**
United States	**131**	**136**	**139**	**127**	**533**

Outcome Measures

Show All Outcome Measures

1. **Primary: Change From Baseline to 24 Week Endpoint in Glycated Hemoglobin (HbA1c) [Time Frame: Baseline, 24 weeks]**

   Show Outcome Measure 1

2. **Secondary: Percentage of Participants Achieving Glycated Hemoglobin (HbA1c) Target Values [Time Frame: 24-week endpoint]**

   Show Outcome Measure 2

3. **Secondary: Percentage of Participants ≥65 Years of Age Achieving Glycated Hemoglobin (HbA1c) Target Concentration [Time Frame: 24-week endpoint]**

   Show Outcome Measure 3

4. **Secondary: Change From Baseline to 24 Week Endpoint in Body Weight [Time Frame: Baseline, 24-weeks]**

   Show Outcome Measure 4

5. **Secondary: Time to Reach Glycated Hemoglobin (HbA1c) Target Values [Time Frame: Baseline through 24 weeks]**

   Show Outcome Measure 5

6. **Secondary: Change From Baseline to 24 Week Endpoint in Fasting Glucose [Time Frame: Baseline, 24 weeks]**

   Show Outcome Measure 6

7. **Secondary: Change From Baseline to 24 Week Endpoint in Fasting Glucose in Participants ≥65 Years of Age [Time Frame: Baseline, 24 weeks]**

   Show Outcome Measure 7

8. **Secondary: Change From Baseline to 24 Week Endpoint in 1,5-anhydroglucitol (1,5-AG) [Time Frame: Baseline, 24 weeks]**

   Show Outcome Measure 8

9. **Secondary: Change From Baseline to 24 Weeks in 7-Point Self-Monitored Blood Glucose (SMBG) Profile [Time Frame: Baseline, 24 weeks]**

   Show Outcome Measure 9

10. **Secondary: Daily Dose of Insulin: Total, Basal and Prandial (Bolus) [Time Frame: 24 weeks]**

    Show Outcome Measure 10

11. **Secondary: Daily Dose of Insulin Per Kilogram of Body Weight: Total, Basal and Prandial (Bolus) [Time Frame: 24 weeks]**

Show Outcome Measure 11

12. **Secondary: The Number of Participants With a Hypoglycemic Episode (Incidence) [Time Frame: Randomization through 24 weeks overall]**

Show Outcome Measure 12

13. **Secondary: The Number of Participants ≥65 Years of Age With Hypoglycemic Episodes (Incidence) [Time Frame: Randomization through 24 weeks overall]**

Show Outcome Measure 13

14. **Secondary: The Rate of Hypoglycemic Episodes [Time Frame: Randomization through 24 weeks overall]**

Show Outcome Measure 14

15. **Secondary: Percentage of Participants With Severe Hypoglycemic Episodes [Time Frame: Randomization up to 24 weeks]**

Show Outcome Measure 15

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
Five (5) randomized participants (3 Study B Q1D, 2 Study B Q3D) from 1 site were excluded from efficacy and safety analyses due to quality issues and validity of the data at that site.

More Information

Hide More Information

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.

The agreement is:

- ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.
- ☑ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.
- ☐ Other disclosure agreement that restricts the right of the PI 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

Responsible Party:	Eli Lilly and Company
ClinicalTrials.gov Identifier:	NCT01215955 History of Changes
Other Study ID Numbers:	13460 **F3Z-MC-IOQC** (Other Identifier: Eli Lilly and Company)
First Submitted:	September 30, 2010
First Posted:	October 7, 2010
Results First Submitted:	January 9, 2014
Results First Posted:	February 27, 2014
Last Update Posted:	April 23, 2014