Trial record **1 of 1** for: F3Z-EW-S020

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Pre-Mix Insulin Lispro Treatment for Type 2 Diabetes Patients Who Consume a Light Breakfast

ClinicalTrials.gov Identifier: NCT00664534

Recruitment Status : Completed
First Posted : April 23, 2008
Results First Posted : December 13, 2011
Last Update Posted : December 13, 2011

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 Glargine Drug: Insulin Lispro Premix (mid-mixture and low-mixture)

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
No text entered.

Reporting Groups

	Description
Glargine	Glargine +/- 1,2 or 3 injections of insulin lispro plus oral antihyperglycemic medications (OAMs)
Premix Insulin Lispro	Premixed Insulin Lispro (mid-mixture or low-mixture)1,2 or 3 injections plus OAMs

Participant Flow: Overall Study

	Glargine	**Premix Insulin Lispro**
STARTED	**173**	**171**
COMPLETED	**132**	**138**

NOT COMPLETED	41	33
Adverse Event	2	3
Lost to Follow-up	6	10
Protocol Violation	10	8
Withdrawal by Subject	7	6
Physician Decision	8	0
Sponsor decision	8	6

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.
No text entered.

Reporting Groups

	Description
Glargine	Glargine +/- 1,2 or 3 injections of insulin lispro plus oral antihyperglycemic medications (OAMs)
Premix Insulin Lispro	Premixed Insulin Lispro (mid-mixture or low-mixture)1,2 or 3 injections plus OAMs
Total	Total of all reporting groups

Baseline Measures

	Glargine	Premix Insulin Lispro	Total
Overall Participants Analyzed [Units: Participants]	173	171	344
	54.24 (8.621)	54.33 (8.944)	54.29 (8.770)

Age [Units: Years] Mean (Standard Deviation)			
Gender [Units: Participants]			
Female	**92**	**84**	**176**
Male	**81**	**87**	**168**
Race/Ethnicity, Customized [Units: Participants]			
Caucasian	**97**	**101**	**198**
African	**2**	**1**	**3**
Hispanic	**44**	**40**	**84**
East Asian	**11**	**10**	**21**
West Asian	**19**	**19**	**38**
Region of Enrollment [Units: Participants]			
Portugal	**7**	**8**	**15**
Egypt	**31**	**33**	**64**
Mexico	**38**	**33**	**71**
Canada	**3**	**4**	**7**
Spain	**18**	**22**	**40**
Romania	**25**	**25**	**50**
Turkey	**13**	**13**	**26**
India	**30**	**28**	**58**
Brazil	**8**	**5**	**13**
Glycosylated Hemoglobin (HbA1c) [Units: Percent glycosylated hemoglobin] Mean (Standard Deviation)	**9.07 (0.988)**	**8.98 (0.945)**	**9.02 (0.966)**

Outcome Measures

Show All Outcome Measures

1. **Primary: Baseline Adjusted Glycosylated Hemoglobin (HbA1c) at Endpoint [Time Frame: 48 weeks]**

   Show Outcome Measure 1

2. **Secondary: Percentage of Participants Using Each Possible Final Insulin Regimen [Time Frame: 48 weeks]**

   Show Outcome Measure 2

3. **Secondary: HbA1c Over Time [Time Frame: 16 weeks, 32 weeks, and 48 weeks]**

   Show Outcome Measure 3

4. **Secondary: Percentage of Patients Achieving HbA1c Less Than or Equal to 6.5% and Less Than or Equal to 7% Over Time [Time Frame: 16 weeks, 32 weeks and 48 weeks]**

   Show Outcome Measure 4

5. **Secondary: 7-point Self-monitored Blood Glucose Profiles [Time Frame: 16 weeks, 32 weeks and 48 weeks]**

   Show Outcome Measure 5

6. **Secondary: Mean Postprandial Blood Glucose Values [Time Frame: Baseline, 16 weeks, 32 weeks and 48 weeks]**

   Show Outcome Measure 6

7. **Secondary: Mean Daily Total, Basal and Prandial Insulin Dose [Time Frame: 16 weeks, 32 weeks and 48 weeks]**

   Show Outcome Measure 7

8. **Secondary: Body Weight Change From Baseline to Endpoint [Time Frame: baseline, 48 weeks]**

   Show Outcome Measure 8

9. **Secondary: Incidence of All Self-reported Hypoglycemic Episodes [Time Frame: Baseline to 48 weeks]**

Show Outcome Measure 9

10. Secondary: Rate Per 30 Days of All Self-reported Hypoglycemic Episodes [Time Frame: Baseline to 48 weeks]

Show Outcome Measure 10

11. Secondary: Number of Participants With Adverse Events [Time Frame: Baseline to 48 weeks]

Show Outcome Measure 11

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
No text entered.

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:	NCT00664534 History of Changes
Other Study ID Numbers:	11806 **F3Z-EW-S020** (Other Identifier: Eli Lilly and Company) CTRI/2009/091/000609 (Registry Identifier: India Registry)
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