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

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A Study of Postprandial Hyperglycemia in Participants With Type 2 Diabetes

ClinicalTrials.gov Identifier: NCT01159938

Recruitment Status : Completed
First Posted : July 12, 2010
Results First Posted : April 3, 2014
Last Update Posted : April 3, 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: Crossover Assignment; Masking: None (Open Label)

Condition:	Diabetes Mellitus, Type 2
Intervention:	Drug: Lispro

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
Participants with type 2 diabetes mellitus (T2DM) were randomized to either a high to low blood glucose sequence or a low to high blood glucose sequence dependent upon whether they received insulin lispro or not in the first study period. Participants were stratified into treatment arms based on their urinary albumin excretion rate (UAER).

Reporting Groups

	Description
Healthy Participants	Healthy participants with normal glucose tolerance and normal UAER did not receive an insulin lispro subcutaneous injection but participated in study assessments. Normal glucose tolerance according to World Health Organization (WHO) criteria was defined as fasting glucose <6.1 millimoles/liter (mmol/L) and 2-hour glucose <7.8 mmol/L. Normal UAER was defined as <20 micrograms per minute (mcg/min) of albumin in the overnight urine collection or <30 milligrams per 24 hours (mg/24h) of albumin in the 24-hour urine collection.
T2DM With Albuminuria, High to Low	T2DM participants with abnormal UAER [albuminuria (defined as urinary albumin)] but

	normal kidney function who did not receive an insulin lispro subcutaneous injection in the first study period and who received an insulin lispro subcutaneous injection prior to a standard breakfast in the second study period. The dosage of insulin lispro was adjusted as needed based on the energy content of the participant's normal breakfast and standard basal insulin dose.
T2DM With Albuminuria, Low to High	T2DM participants with abnormal UAER (albuminuria) but normal kidney function who received an insulin lispro subcutaneous injection prior to a standard breakfast in the first study period and who did not receive an insulin lispro subcutaneous injection in the second study period. The dosage of insulin lispro was adjusted as needed based on the energy content of the participant's normal breakfast and standard basal insulin dose.
T2DM With Normal UAER, High to Low	T2DM participants with normal UAER who did not receive an insulin lispro subcutaneous injection in the first study period and who received an insulin lispro subcutaneous injection prior to a standard breakfast in the second study period. The dosage of insulin lispro was adjusted as needed based on the energy content of the participant's normal breakfast and standard basal insulin dose.
T2DM With Normal UAER, Low to High	T2DM participants with normal UAER who received an insulin lispro subcutaneous injection prior to a standard breakfast in the first study period and who did not receive an insulin lispro subcutaneous injection in the second study period. The dosage of insulin lispro was adjusted as needed based on the energy content of the participant's normal breakfast and standard basal insulin dose.

Participant Flow for 2 periods

Period 1: First Study Period

	Healthy Participants	T2DM With Albuminuria, High to Low	T2DM With Albuminuria, Low to High	T2DM With Normal UAER, High to Low	T2DM With Normal UAER, Low to High
STARTED	26	11	11	12	12
Received at Least 1 Dose of Study Drug	0	11	11	12	12
Safety and Efficacy Analysis Population	25 [1]	11	11 [2]	12	12
COMPLETED	26	11	10	12	12
NOT COMPLETED	0	0	1	0	0
Protocol Violation (Microalbuminuria)	0	0	1	0	0

[1] One healthy participant completed study but was excluded from analyses (major protocol violation).

[2] Microalbuminuria relaxed with protocol amendment. T2DM albuminuria participant included in analyses.

Period 2: Second Study Period

	Healthy Participants	T2DM With Albuminuria, High to Low	T2DM With Albuminuria, Low to High	T2DM With Normal UAER, High to Low	T2DM With Normal UAER, Low to High
STARTED	0	11	10	12	12
COMPLETED	0	11	10	12	12
NOT COMPLETED	0	0	0	0	0

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.
All enrolled participants, with the exception of 1 healthy participant who completed the study but was later excluded from analyses due to major protocol violation.

Reporting Groups

	Description
Healthy Participants	Healthy participants with normal glucose tolerance and normal urinary albumin excretion rate (UAER) did not receive an insulin lispro subcutaneous injection but participated in study assessments. Normal glucose tolerance according to World Health Organization (WHO) criteria was defined as fasting glucose <6.1 millimoles/liter (mmol/L) and 2-hour glucose <7.8 mmol/L. Normal UAER was defined as <20 micrograms per minute (mcg/min) of albumin in the overnight urine collection or <30 milligrams per 24 hours (mg/24h) of albumin in the 24-hour urine collection.
T2DM With Albuminuria	T2DM participants with abnormal UAER [albuminuria (defined as urinary albumin)] but normal kidney function who received an insulin lispro subcutaneous injection prior to a standard breakfast in the first study period and who did not receive an insulin lispro subcutaneous injection prior to standard breakfast in the second study period (low to high sequence) or participants who did not receive an insulin lispro subcutaneous injection prior to a standard breakfast in the first study period and who received an insulin lispro subcutaneous injection prior to a standard breakfast in the second study period (high to low sequence). The dosage of insulin lispro was adjusted as needed based on the energy content of the participant's normal breakfast and standard basal insulin dose.
T2DM With Normal UAER	T2DM participants with normal UAER who received an insulin lispro subcutaneous injection prior to a standard breakfast in the first

	study period and who did not receive an insulin lispro subcutaneous injection prior to a standard breakfast in the second study period (low to high sequence) or participants who did not receive an insulin lispro subcutaneous injection prior to a standard breakfast in the first study period and who received an insulin lispro subcutaneous injection prior to a standard breakfast in the second study period (high to low sequence). The dosage of insulin lispro was adjusted as needed based on the energy content of the participant's normal breakfast and standard basal insulin dose.
Total	Total of all reporting groups

Baseline Measures

	Healthy Participants	T2DM With Albuminuria	T2DM With Normal UAER	Total
Overall Participants Analyzed [Units: Participants]	**25**	**22**	**24**	**71**
Age [Units: Years] Mean (Standard Deviation)	**58.8 (6.6)**	**61.2 (4.9)**	**63.7 (5.2)**	**61.2 (5.9)**
Gender [Units: Participants]				
Female	**0**	**0**	**0**	**0**
Male	**25**	**22**	**24**	**71**
Race/Ethnicity, Customized [Units: Participants]				
White	**25**	**22**	**24**	**71**
Region of Enrollment [Units: Participants]				
Finland	**25**	**22**	**24**	**71**

Outcome Measures

Show All Outcome Measures

1. Primary: Postprandial Pulse Wave Velocity (PWV) in Type 2 Diabetes Mellitus (T2DM) Participants at 30 Minutes (Mins) Pre-Breakfast [Time Frame: 30 mins (pre-breakfast)]

   Show Outcome Measure 1

2. Primary: Postprandial Pulse Wave Velocity (PWV) in Type 2 Diabetes Mellitus (T2DM) Participants at 60 Minutes (Mins) Post-Breakfast [Time Frame: 60 mins (post-breakfast)]

   Show Outcome Measure 2

3. Primary: Postprandial Pulse Wave Velocity (PWV) in Type 2 Diabetes Mellitus (T2DM) Participants at 120 Minutes (Mins) Post-Breakfast [Time Frame: 120 mins (post-breakfast)]

   Show Outcome Measure 3

4. Primary: Postprandial Pulse Wave Velocity (PWV) in Type 2 Diabetes Mellitus (T2DM) Participants at 180 Minutes (Mins) Post-Breakfast [Time Frame: 180 mins (post-breakfast)]

   Show Outcome Measure 4

5. Primary: Postprandial Pulse Wave Velocity (PWV) in Type 2 Diabetes Mellitus (T2DM) Participants at 240 Minutes (Mins) Post-Breakfast [Time Frame: 240 mins (post-breakfast)]

   Show Outcome Measure 5

6. Secondary: Change in Pulse Wave Amplitude (PWA) [Time Frame: 30 mins (pre-breakfast), 60, 120, 180 and 240 mins (post-breakfast)]

   Show Outcome Measure 6

7. Secondary: Change in Peripheral Artery Tonometry (PAT) [Time Frame: 30 mins (pre-breakfast), 120 and 240 mins (post-breakfast)]

   Show Outcome Measure 7

8. **Secondary: Change in QT Interval on Electrocardiogram (ECG) [Time Frame: 30 mins (pre-breakfast), 60, 120, 180 and 240 mins (post-breakfast)]**

Show Outcome Measure 8

9. **Secondary: Change in Blood Glucose (BG) [Time Frame: 30 mins (pre-breakfast), 50, 110 ,170, and 230 mins (post-breakfast)]**

Show Outcome Measure 9

10. **Secondary: Change in Postprandial Pulse Wave Velocity (PWV) [Time Frame: 30 mins (pre-breakfast), 60, 120, 180 and 240 mins (post-breakfast)]**

Show Outcome Measure 10

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

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

Gordin D, Saraheimo M, Tuomikangas J, Soro-Paavonen A, Forsblom C, Paavonen K, Steckel-Hamann B, Vandenhende F, Nicolaou L, Pavo I, Koivisto V, Groop PH. Influence of Postprandial Hyperglycemic Conditions on Arterial Stiffness in Patients With Type 2 Diabetes. J Clin Endocrinol Metab. 2016 Mar;101(3):1134-43. doi: 10.1210/jc.2015-3635. Epub 2016 Jan 5.

Muka T, de Jonge EA, Kiefte-de Jong JC, Uitterlinden AG, Hofman A, Dehghan A, Zillikens MC, Franco OH, Rivadeneira F. The Influence of Serum Uric Acid on Bone Mineral Density, Hip Geometry, and Fracture Risk: The Rotterdam Study. J Clin Endocrinol Metab. 2016 Mar;101(3):1113-22. doi: 10.1210/jc.2015-2446. Epub 2015 Dec 18.

Responsible Party: Eli Lilly and Company

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