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

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Comparison of Two Basal Insulins for Patients With Type 2 Diabetes on Anti-Hyperglycemic Medications (IOPE) (IOPE)

ClinicalTrials.gov Identifier: NCT00510952

Recruitment Status : Completed
First Posted : August 3, 2007
Results First Posted : November 3, 2009
Last Update Posted : October 21, 2010

Sponsor:
Eli Lilly and Company

Information provided by:
Eli Lilly and Company

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How to Read a Study Record

Study Description

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Brief Summary:

The purpose of this study is to examine the effectiveness and safety of insulin lispro protamine suspension (ILPS) as compared to insulin glargine as basal insulin therapy in adults with type 2 diabetes.

Condition or disease	Intervention/treatment	Phase
Diabetes Mellitus, Type 2	Drug: Insulin Lispro Protamine Suspension Drug: Insulin Glargine	Phase 3

Study Design

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Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	471 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	The PERSISTENT Trial: A Prospective Randomized Trial Comparing Insulin Lispro Protamine Suspension to Insulin Glargine in Patients With Type 2 Diabetes on Anti-hyperglycemic Medications
Study Start Date :	August 2007
Primary Completion Date :	October 2008
Study Completion Date :	October 2008

Resource links provided by the National Library of Medicine

Genetics Home Reference related topics:
Type 2 diabetes

Drug Information available for: Insulin Protamine Insulin human Insulin lispro Insulin glargine

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Lispro Insulin Lispro protamine suspension: Patient adjusted dose, once daily (QD) or twice daily (BID), injected subcutaneous (SC) x 24 weeks	Drug: Insulin Lispro Protamine Suspension Patient adjusted dose, once daily (QD) or twice daily (BID), injected subcutaneous (SC) x 24 weeks Other Names: • Insulin Lispro Protamine Suspension (ILPS) • Neutral Protamine Lispro (NPL) • Humalog
Active Comparator: Glargine Insulin glargine: Patient adjusted dose, once daily (QD), injected subcutaneous (SC) x 24 weeks	Drug: Insulin Glargine Patient adjusted dose, once daily (QD), injected subcutaneous (SC) x 24 weeks

Outcome Measures

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Primary Outcome Measures :

1. Change From Baseline to 24 Week Endpoint in Hemoglobin A1c (HbA1c)
   [Time Frame: Baseline, 24 Weeks]

Secondary Outcome Measures :

1. Actual and Change From Baseline to 12 Week and 24 Week Endpoint in HbAlc Value
   [Time Frame: Baseline, 12 Weeks, 24 Weeks]
2. Percentage of Patients With HbAlc Less Than 7.0 Percent and HbAlc Less Than or Equal to 6.5 Percent at Endpoint [Time Frame: 24 weeks]

   Percentage of patients achieving Hemaglobin A1c (HbA1c) targets of less than 7% and less than or equal to 6.5% at endpoint.

3. Glycemic Variability at Endpoint [Time Frame: 24 weeks]

Glycemic variability was measured by standard deviation (SD) value of fasting blood glucose as measured by intra-patient glycemic variability (determined by the 7-point self-monitoring blood glucose (SMBG) profiles at endpoint) based on the actual morning pre-meal blood glucose.

4. 7-Point Self-Monitored Blood Glucose (SMBG) Profile at Endpoint [Time Frame: 24 weeks]

   Actual measurements and daily mean blood glucose levels at endpoint.

5. Number of Participants With Self-Reported Hypoglycemic Episodes (Including All, Nocturnal, and Severe Hypoglycemia) Overall [Time Frame: Baseline to 24 weeks]

   Overall: any time after randomization. Hypoglycemic: any time patient experienced sign/symptom associated with hypoglycemia, or had old Roche blood glucose level <7 mg/dL. Nocturnal: any hypoglycemic event that occurred between bedtime and waking. Severe Hypoglycemia: event with symptoms consistent with neuroglycopenia in which patient requires assistance, and is associated with either a Roche blood glucose value <2.8 millimoles/liter or prompt recovery after oral carbohydrate, glucagon, or intravenous glucose.

6. 1-Year Adjusted Rates of Self-Reported Hypoglycemic Episodes (Including All, Nocturnal, and Severe) Overall [Time Frame: Baseline to 24 weeks]

   Overall: any time after randomization. Hypoglycemic: any time patient experienced sign/symptom associated with hypoglycemia, or had old Roche blood glucose level <7 mg/dL. Nocturnal: any hypoglycemic event that occurred between bedtime and waking. Severe: event with symptoms consistent with neuroglycopenia in which patient requires assistance, and is associated with: a Roche blood glucose value <2.8 mmol/L or prompt recovery after oral carbohydrate, glucagon, or IV glucose. 1-year adjusted rate=(total number of episodes between 2 time intervals/number of days between intervals) X 365.25 days.

7. 30-Day Adjusted Rates of Self-Reported Hypoglycemic Episodes (Including All, Nocturnal, and Severe) Overall [Time Frame: Baseline to 24 Weeks]

   Overall: any time after randomization. Hypoglycemic: any time patient experienced sign/symptom associated with hypoglycemia, or had old Roche blood glucose level <7 mg/dL. Nocturnal: any hypoglycemic event that occurred between bedtime and

waking. Severe: event with symptoms consistent with neuroglycopenia in which patient requires assistance, and is associated with: a Roche blood glucose value <2.8 mmol/L or prompt recovery after oral carbohydrate, glucagon, or IV glucose. 30-day adjusted rate=(total number of episodes between 2 time intervals/number of days between intervals) X 30 days.

8. Change in Absolute Body Weight (kg) From Baseline to 24 Week Endpoint
   [Time Frame: Baseline, 24 weeks]
9. Total Daily Insulin Dose (Units) at Endpoint [Time Frame: 24 weeks]

   Insulin dose at endpoint was analyzed by 24-hour total daily insulin (units).

10. Total Daily Insulin Dose Per Body Weight (Units/Kilograms) at Endpoint
    [Time Frame: 24 Weeks]

    Insulin dose at endpoint was analyzed by 24-hour total daily insulin per body weight (units/kilograms).

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Have type 2 diabetes mellitus for at least 1 year.
- Are greater than or equal to 18 years old.
- Have been receiving oral antihyperglycemic medications (OAMs), without insulin, for at least 3 months immediately prior to the study and have been on stable doses of at least 2 of the following OAMs for the 6 weeks prior to Visit 1: Metformin- Sulfonylureas-Dipeptidyl peptidase-IV (DPP-IV) inhibitors-Thiazolidinediones (TZDs)
- Have a hemoglobin A1c (HbA1c) greater than or equal to 7.5% and less than or equal to 10.0%, as measured by a central laboratory before Visit 2.
- Body mass index (BMI) greater than or equal to 25 and less than or equal to 45 kg/meter squared.

Exclusion Criteria:

- Have used insulin therapy (outside of pregnancy) any time in the past 2 years, except for short-term treatment of acute conditions, and up to a maximum of 4 weeks.
- Have taken any glucose-lowering medications not included in Inclusion Criterion #3; (for example, acarbose, miglitol, pramlintide, exenatide, repaglinide, or nateglinide) in the past 3 months before Visit 1.
- Have had more than 1 episode of severe hypoglycemia, within 6 months prior to entry into the study, or is currently diagnosed as having hypoglycemia unawareness.
- Have had 2 or more emergency room visits or hospitalizations due to poor glucose control in the past 6 months.
- Are pregnant or intend to become pregnant during the course of the study or are sexually active women of childbearing potential not actively practicing birth control by a method determined by the investigator to be medically acceptable.

Contacts and Locations

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Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT00510952***

Locations

United States, Arkansas

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY
Jonesboro, Arkansas, United States, 72401

United States, California

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY
Huntington Park, California, United States, 90255

United States, Florida

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY
Miami, Florida, United States, 33145

United States, Georgia

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY
Atlanta, Georgia, United States, 30312

United States, Indiana

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY
Indianapolis, Indiana, United States, 46222

United States, Kansas

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY
Wichita, Kansas, United States, 67208

United States, Kentucky

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY
Lexington, Kentucky, United States, 40502

United States, Louisiana

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY
Slidell, Louisiana, United States, 70458

United States, New Jersey

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY
Toms River, New Jersey, United States, 08755

United States, New York

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Brooklyn, New York, United States, 11203

United States, Washington

For additional information regarding investigative sites for this trial, contact 1-877-CTLILL
Tacoma, Washington, United States, 98405

Brazil

For additional information regarding investigative sites for this trial, contact 1-877-CTLILL
Brasilia, Brazil, 71625-009

For additional information regarding investigative sites for this trial, contact 1-877-CTLILL
Fortaleza, Brazil, 60430-350

For additional information regarding investigative sites for this trial, contact 1-877-CTLILL
Joinville, Brazil, 89201-260

For additional information regarding investigative sites for this trial, contact 1-877-CTLILL
Sao Paulo, Brazil, 01244-030

Canada, British Columbia

For additional information regarding investigative sites for this trial, contact 1-877-CTLILL
Victoria, British Columbia, Canada, V8R 6V4

Puerto Rico

For additional information regarding investigative sites for this trial, contact 1-877-CTLILL
Ponce, Puerto Rico, 00716

Sponsors and Collaborators

Eli Lilly and Company

Investigators

Study Director: Call 1-877-CTLILLY (1-877-285-4559) or 1-317-615-4559 Mon-Fri 9 AM-5 PM

More Information

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Additional Information:

Lilly Clinical Trial Registry EXIT

Publications of Results:

Strojek K, Shi C, Carey MA, Jacober SJ. Addition of insulin lispro protamine suspension or insulin glargine to oral type 2 diabetes regimens: a randomized trial. Diabetes Obes Metab. 2010 Oct;12(10):916-22. doi: 10.1111/j.1463-1326.2010.01257.x.

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

Qu Y, Jacober SJ, Zhang Q, Wolka LL, DeVries JH. Rate of hypoglycemia in insulin-treated patients with type 2 diabetes can be predicted from glycemic variability data. Diabetes Technol Ther. 2012 Nov;14(11):1008-12. doi: 10.1089/dia.2012.0099.

Responsible Party:	Chief Medical Officer, Eli Lilly
ClinicalTrials.gov Identifier:	NCT00510952 History of Changes
Other Study ID Numbers:	11813 **F3Z-MC-IOPE** (Other Identifier: Eli Lilly and Company)
First Posted:	August 3, 2007 Key Record Dates
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Last Verified:	October 2010

Keywords provided by Eli Lilly and Company:
diabetes
type 2

Additional relevant MeSH terms:

Diabetes Mellitus	Insulin Lispro
Diabetes Mellitus, Type 2	Hypoglycemic Agents
Glucose Metabolism Disorders	Protamines
Metabolic Diseases	Physiological Effects of Drugs
Endocrine System Diseases	Heparin Antagonists
Insulin, Globin Zinc	Molecular Mechanisms of Pharmacological Action
Insulin	
Insulin Glargine	Coagulants