

Unique Protocol ID: 13183

Secondary ID: I4B-FW-GPCB

Brief Title: A Multiple-Ascending Dose Study in Type 2 Diabetes Mellitus Patients

Official Title: Safety, Tolerability, Pharmacokinetics and Pharmacodynamic Effects of Multiple Escalating Oral Doses of LY2393910 in Patients With Type 2 Diabetes Mellitus

Study Type: Interventional

Sponsor: Eli Lilly and Company

Collaborators: N/A

Brief Summary: The study drug LY2393910 is being evaluated as a possible treatment for diabetes. The primary purpose of a subject's participation in this study is to help answer the following research question(s), and not to provide treatment for diabetes:

- The safety of LY2393910 and any side effects that might be associated with it following 2 weeks of doses
- How long it takes the body to absorb and remove LY2393910 following dosing over 2 weeks
- How daily dosing of LY2393910 affects blood levels of sugar (glucose), insulin and other naturally occurring substances in your body
- How daily dosing of LY2393910 affects the cells that produce insulin
- Any differences in the above between LY2393910 taken as daily doses in the morning or in the evening

Overall Status: Recruiting

Study Start Date: March 2010

Study Completion Date: August 2010

Study Design:

Primary Purpose: Other

Study Phase: Phase 1

Interventional Model: Parallel Assignment

Number of Arms: 5

Masking: Double Blind (Subject, Investigator)

Allocation: Randomized

Control: Placebo Control

Endpoint Classification: Safety Study

Enrollment: 86 [Anticipated]

Primary Outcome Measure:

Measure: Clinically Significant Effects

Timeframe: Over four weeks

Secondary Outcome Measure:

Measure: Pharmacokinetics of LY2393910, Area Under the Curve (AUC)

Timeframe: From predose Day 1 up until Day 19

Measure: Pharmacokinetics of LY2393910, maximum concentration (Cmax)

Timeframe: From predose Day 1 up until Day 19

Measure: Change in glucagon

Timeframe: From baseline to Day 28

Measure: Change in GLP-1

Timeframe: From baseline to Day 28

Measure: Change in insulin and c-peptide

Timeframe: From baseline to Day 14

Measure: Change in pro-insulin

Timeframe: From baseline to Day 14

Measure: Change in glucose

Timeframe: From baseline to Day 28

Condition(s): Diabetes Mellitus, Type 2

Arms	Assigned Interventions
Experimental: 20 mg LY2393910	Drug: LY2393910 as capsules, administered orally once daily for two weeks
Experimental: 60 mg LY2393910	Drug: LY2393910 as capsules, administered orally once daily for two weeks
Experimental: 150 mg LY2393910	Drug: LY2393910 as capsules, administered orally once daily for two weeks
Experimental: 450 mg LY2393910	Drug: LY2393910 as capsules, administered orally once daily for two weeks
Placebo Comparator: Placebo	Drug: Placebo as capsules, administered orally once daily for two weeks

Eligibility Criteria:

Inclusion Criteria:

- Diagnosis of type 2 diabetes mellitus as determined by the investigator
- Must be on a stable treatment regimen (maintained on diet/exercise therapy with or without metformin) for at least 4 weeks prior to study entry
- Have a glycated haemoglobin (HbA1c) value greater than or equal to 6.5% and less than or equal to 10.0% on a stable treatment regimen
- Weigh 45.0 kg or more
- Have a Body Mass Index (BMI) greater than or equal to 18.5 and less than or equal to 40.0 kg/m²
- Are willing and able to conduct self-blood glucose monitoring tests

Exclusion Criteria:

- Are currently enrolled in, or discontinued within the last 30 days from a clinical trial involving use of an investigational drug or device other than the study drug used in this study, or are concurrently enrolled in any other type of medical research judged not to be compatible with this study.
- Use of insulin for diabetic control for more than 6 consecutive days within 1 year prior to study entry
- Use of thiazolidinediones within 3 months, or other oral anti-diabetics (OADs), apart from metformin, within 1 month prior to study entry. Metformin is acceptable for this study

- Previous myocardial infarction, stroke or transient ischaemic event ('TIA'), or clinically significant coronary events or symptoms within 6 months prior to study entry
- Subjects who have any evidence of heart insufficiency, hypokalaemia, family history of long-QT-syndrome or are receiving other drugs which extend the QT interval
- Clinically significant peripheral vascular disease
- Clinical evidence of active diabetic proliferative retinopathy
- Known significant autonomic neuropathy
- Any patient having experienced a keto-acidotic episode requiring hospitalisation in the last 6 months
- Symptomatic hyperglycemia exhibited by significant osmotic symptoms (polyuria or polydipsia), unanticipated weight loss or dehydration
- Evidence of hepatitis B and/or positive hepatitis B surface antigen, at screening
- Subjects who have an average weekly alcohol intake that exceeds 21 units per week (males) and 14 units per week (females)
- Subjects who are heavy smokers (> 10 cigarettes, or equivalent, per day) or are unable or unwilling to refrain from nicotine during CRU admissions

Exclusion Criteria for EU Site only --

- Regular use of known drugs of abuse and/or positive findings on urinary drug screening
- Evidence of human immunodeficiency virus (HIV) and/or positive HIV antibodies
- Evidence of hepatitis C and/or positive hepatitis C antibodies

Minimum Age: 21 years

Maximum Age: 70 years

Gender: Both

Contact for Public Queries: There may be multiple sites in this clinical trial. 1-877-CTLILLY (1-877-285-4559) or (1-317-615-4559)

Contact for Scientific Queries: Call 1-877-CTLILLY (1-877-285-4559) or 1-317-615-4559 Mon - Fri 9 AM - 5 PM Eastern time (UTC/GMT - 5 hours, EST)

Locations:

Lilly Clinical Trial Site
Singapore, Singapore
Active, Not Recruiting

Lilly Clinical Trial Site
Neuss, Germany
Recruiting