

Unique Protocol ID: 11975

Secondary IDs: H8O-FW-GWCL

Brief Title: A Study of Exenatide Long-Acting Release in Chinese Subjects With Type 2 Diabetes Mellitus

Official Title: Single and Multiple Dose Pharmacokinetics, Safety and Tolerability of Exenatide (LY2148568) Long-Acting Release in Chinese Subjects With Type 2 Diabetes Mellitus Study Type: Interventional

Sponsor: Eli Lilly and Company

Brief Summary: The purposes of this study are (1) to assess the pharmacokinetics of 2.0 mg exenatide Long-Acting Release (LAR) in native Chinese subjects with Type 2 diabetes (T2DM) mellitus following single and multiple weekly subcutaneous injections; (2) to observe the safety and tolerability of 2.0 mg exenatide LAR in native Chinese subjects with T2DM following single and multiple weekly subcutaneous injections

Overall Status: Active, Not Recruiting

Study Start: October 2009

Study Completion Date: May 2010 [Anticipated]

Study Design:

Primary Purpose: Treatment

Study Phase: Phase 1

Interventional Model: Single Group Assignment

Number of Arms: 1

Masking: Open Label

Allocation: Non-Randomized

Control: Uncontrolled

Endpoint Classification: Pharmacokinetics Study

Enrollment: 40 [Anticipated]

Primary Outcome Measure:

Measure: Pharmacokinetics Cmax of 2.0 mg exenatide LAR in native Chinese subjects with Type 2 diabetes mellitus (T2DM)

Timeframe: 20 weeks

Measure: Pharmacokinetics AUC of 2.0 mg exenatide LAR in native Chinese subjects with Type 2 diabetes mellitus (T2DM)

Timeframe: 20 weeks

Secondary Outcome Measure:

Measure: Safety and tolerability of 2.0 mg exenatide LAR in native Chinese subjects with T2DM

Timeframe: 20 weeks

Condition(s): Diabetes Mellitus, Type 2

Keywords:

type 2 diabetes mellitus

Pharmacokinetics

Exenatide

Safety

Tolerability

Chinese

Arms	Assigned Interventions
Experimental: exenatide LAR	Drug: exenatide LAR 2.0 mg exenatide LAR subcutaneous injection, once weekly, for 10 weeks

Eligibility Criteria:

Inclusion Criteria:

- Male or female subjects with mild T2DM treated with diet modification and exercise alone or in combination with a stable (in Investigator's opinion) regimen of metformin only. The T2DM diagnosis shall be confirmed clinically by the Investigator, and should be consistent with the World Health Organization (WHO) criteria for diagnosis and classification of diabetes.

- Between 20 to 75 years of age inclusive at screening.
- This inclusion criterion applies to females of child-bearing potential (not surgically sterilized and between menarche and 1-year postmenopause) only: Test negative for pregnancy at the time of screening; Intend not to become pregnant during the study; Are sexually inactive or have practiced a reliable method of birth control (for example, use of oral contraceptives or levonorgestrel; diaphragms with contraceptive jelly; cervical caps with contraceptive jelly; condoms with contraceptive foam; intrauterine devices; partner with vasectomy; or abstinence) for at least 6 weeks prior to screening; Agree to continue to use a reliable method of birth control (as determined by the investigator) during the study.
- Have a body weight of $\geq 45\text{kg}$ and body mass index (BMI) of 18.5 kg/m^2 to 35 kg/m^2 inclusive at screening.

Exclusion Criteria:

- Have a known allergy or hypersensitivity to exenatide, exenatide LAR or excipients contained in these agents.
- Persons who have previously been treated with LY2148568 (exenatide) or related compounds.
- History or presence of cardiovascular, respiratory, hepatic, renal, gastrointestinal, endocrine, hematological or neurological disorders capable of significantly altering the absorption, metabolism or elimination of drugs; of constituting a risk when taking the study medication; or of interfering with the interpretation of data.
- Have hypertension requiring more than single-agent therapy, or blood pressure persistently (on ≥ 2 separate occasions) $> 145/85$ on monotherapy.
- Have a history of angina, revascularisation, myocardial infarction or heart failure.
- Have evidence of poorly-controlled diabetes mellitus or evidence of significant diabetes-related complications such as: Plasma glucose $\geq 11.1\text{ mmol/L}$ at the screening visit; HbA1c $> 7.5\%$; History of hypoglycaemic or hyperglycaemic coma within 1 year prior to screening; Clinical evidence of active diabetic proliferative retinopathy or macular oedema; Known significant autonomic neuropathy as evidenced by urinary retention, orthostatic hypotension, diabetic diarrhea or gastroparesis.
- Impaired renal function (serum creatinine $>125\text{ }\mu\text{mol/L}$ in women, $>132\text{ }\mu\text{mol/L}$ in men).
- An abnormality in the 12-lead ECG that, in the opinion of the investigator, increases the risks associated with participating in the study.
- Evidence of significant active neuropsychiatric disease.
- Use of over-the counter or prescription medication (other than thyroid replacement therapy, metformin, antihypertensive medication, lipid-lowering agents aspirin or paracetamol/acetaminophen) 7 and 14 days, respectively prior to dosing. If this situation arises, inclusion of an otherwise suitable volunteer may occur if permitted by the investigator and sponsor.
- Have significant active haematological disease and/or blood donation of more than 400 mL within the last 6 months.

- Have a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia (MEN) 2A or 2B.
- Within 3 years of the screening, have had clinical symptoms associated with cholelithiasis (e.g. cholecystitis or biliary colic)

Minimum Age: 20

Maximum Age: 75

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
Beijing, China
Active, Not Recruiting