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Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies.

Completed

A Study of Tirzepatide (LY3298176) in Healthy Participants and Participants With Type 2 Diabetes (T2DM)

ClinicalTrials.gov ID NCT02759107

Sponsor Eli Lilly and Company

Information provided by Eli Lilly and Company (Responsible Party)

Last Update Posted 2024-01-16

Study Overview

Brief Summary

The main purposes of this study are to determine:

- The safety of tirzepatide and any side effects that might be associated with it.
- How much tirzepatide gets into the bloodstream and how long it takes the body to get rid of it.
- How tirzepatide affects the levels of blood sugar.

This study includes 3 parts (A, B and C). Part A involves a single dose of tirzepatide taken as a subcutaneous (SC) injection just under the skin and will be approximately 10 weeks in duration, including screening. Parts B and C involve 4 doses of tirzepatide taken once weekly (over 4 weeks) as a SC injection just under the skin and is approximately 12-14 weeks in duration, including screening. Each participant will enroll in only one part.

Study Start (Actual)
2016-05-11

Primary Completion (Actual)
2017-06-26

Study Completion (Actual)
2017-06-26

Enrollment (Actual)
142

Study Type
Interventional

Feedback

Eli Lilly & Co.
Exhibit 2009
EMPOWER v. Eli Lilly
IPR2025-01024
Ex. 2009-001

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This study includes 3 parts (A, B and C). Part A involves a single dose of tirzepatide taken as a subcutaneous (SC) injection just under the skin and will be approximately 10 weeks in duration, including screening. Parts B and C involve 4 doses of tirzepatide taken once weekly (over 4 weeks) as a SC injection just under the skin and is approximately 12-14 weeks in duration, including screening. Each participant will enroll in only one part.

This study is for research purposes only, and is not intended to treat any medical condition.

Official Title

A Single- and Multiple-Ascending Dose Study in Healthy Subjects to Investigate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of LY3298176 and Multiple Doses in Patients With Type 2 Diabetes Mellitus

Conditions

Healthy | Type 2 Diabetes Mellitus (T2DM)

Intervention / Treatment

- Drug: Tirzepatide
- Drug: Placebo
- Drug: Dulaglutide

Other Study ID Numbers

- 16119
- I8F-MC-GPGA (Other Identifier) (OTHER: Eli Lilly and Company)

2017-06-26

Enrollment (Actual)

142

Study Type

Interventional

Phase

Phase 1

Resource links provided by the National Library of Medicine NIH NLM

MedlinePlus Genetics related topics: Type 2 diabetes

Drug Information available for: Dulaglutide Tirzepatide

FDA Drug and Device Resources

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the Contacts and Locations section in How to Read a Study Record.

This study has 2 locations

United States

Florida Locations

South Miami, Florida, United States, 33143
Miami Research Associates

Singapore

Singapore, Singapore, 117597
For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri, 9 AM to 5 PM Eastern Time (UTC/GMT - 5 hours, EST) or speak with your personal physician.

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Singapore

Singapore, Singapore, 117597
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Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies.

Eligibility Criteria

Description

Inclusion Criteria:

- Healthy participants (Parts A and B) and participants with T2DM diagnosed at least 1 year before enrollment (Part C)
- Have a screening body mass index (BMI) of greater than 18.5 and less than or equal to 40.0 kilograms per meter squared (kg/m²), inclusive
- Participants with T2DM (Part C only): have T2DM controlled with diet and exercise alone or are stable on a single oral antidiabetic medication (metformin for at least 30 days or sulfonylureas). Participants receiving sulfonylureas may participate only if this treatment is stopped for at least 6 weeks before dosing with study drug

Exclusion Criteria:

- Have known allergies to tirzepatide, glucagon-like peptide (GLP)-1 analogs, or related compounds
- Have an abnormality in the 12-lead electrocardiogram (ECG) at screening that, in the opinion of the investigator, increases the risks associated with participating in the study
- Have a history or presence of pancreatitis (history of chronic pancreatitis or idiopathic acute pancreatitis), elevation in serum amylase or lipase (greater than 2-fold the upper limit of normal [ULN]) or gastrointestinal (GI) disorder (for example, relevant esophageal reflux or gall bladder disease) or any GI disease which impacts gastric emptying (for example, gastric bypass surgery, pyloric stenosis, with the exception of appendectomy) or could be aggravated by glucagon-like peptide-1 (GLP-1) analogs or dipeptidyl peptidase (DPP)-IV inhibitors

Participants with T2DM (Part C only)

- Have had more than 1 episode of severe hypoglycemia, as defined by the American Diabetes Association criteria, within 6 months before entry into the study or has a history of hypoglycemia unawareness or poor recognition of hypoglycemic symptoms

All Study Participants (Parts B and C only)

- have known allergies to tirzepatide, GLP-1 analogs, or related compounds, or acetaminophen

Ages Eligible for Study

21 Years to 70 Years (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

Yes

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hypoglycemic symptoms

All Study Participants (Parts B and C only)

- have known allergies to tirzepatide, GLP-1 analogs, or related compounds, or acetaminophen

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

Expand all / Collapse all

How is the study designed?

Design Details

Primary Purpose : Basic Science
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Tirzepatide (Part A) Participants received escalating single doses of either 0.25 milligram (mg) or 0.5mg or 1mg, or 2.5mg or 5mg or 8mg Tirzepatide by subcutaneous injection.	Drug: Tirzepatide • Administered SC • Other Names: ◦ LY3298176
Placebo Comparator: Placebo (Part A) Participants received single dose of placebo by subcutaneous injection.	Drug: Placebo • Administered SC
Experimental: Tirzepatide (Part B) Participants received fixed doses of either 0.5mg or 1.5mg or 4.5mg Tirzepatide once weekly for four weeks or titrated doses of 5mg, 5mg, 8mg and 10mg Tirzepatide once weekly for four weeks by subcutaneous injection.	Drug: Tirzepatide • Administered SC • Other Names: ◦ LY3298176
Placebo Comparator: Placebo (Part B) Participants received placebo once weekly for four weeks by subcutaneous injection.	Drug: Placebo • Administered SC
Active Comparator: Dulaglutide	Drug: Dulaglutide

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B) Participants received placebo once weekly for four weeks by subcutaneous injection.	• Administered SC
Active Comparator: Dulaglutide (Part B) Participants received 1.5mg Dulaglutide once weekly for four weeks by subcutaneous injection.	Drug: Dulaglutide • Administered SC • Other Names: ◦ Trulicity®
Experimental: Tirzepatide (Part C) Participants received fixed doses of either 0.5mg or 5mg Tirzepatide once weekly for four weeks or titrated doses of 5mg,5mg,10mg,10mg or 5mg,5mg,10mg,15mg Tirzepatide once weekly for four weeks by subcutaneous injection	Drug: Tirzepatide • Administered SC • Other Names: ◦ LY3298176
Placebo Comparator: Placebo (Part C) Participants received placebo once weekly for four weeks by subcutaneous injection.	Drug: Placebo • Administered SC

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With One or More Serious Adverse Event(s) (SAEs)	Number of participants with one or more SAEs considered by the investigator to be related to study drug administration. A summary of SAEs and other non-serious adverse events (AEs), regardless of causality, were reported in the Reported Adverse Events module	Baseline through Day 43 (Part A) and Day 57 (Part B and C)

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Pharmacokinetics (PK): Area Under the Concentration Versus Time Curve (AUC) of Tirzepatide in Part A.	Area under the concentration versus time curve from zero to infinity (AUC [0-∞]) of Tirzepatide in Part A.	Predose, 8hours(h), 24h,48h,72h, 96h,120h,168 h,336h postdose, day 29, day 43
Pharmacokinetics (PK):	Area under the concentration versus time curve during 1 dosing	Predose

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Time Curve (AUC) of Tirzepatide in Part A.		96h,120h,168 h,336h postdose, day 29, day 43
Pharmacokinetics (PK): Area Under the Concentration Versus Time Curve (AUC) of Tirzepatide in Part B	Area under the concentration versus time curve during 1 dosing interval (AUC [0-τ]) of Tirzepatide in Part B. τ equals 168 hours.	Predose, 8hours(h), 24h,48h,72h, 168h postdose
Pharmacokinetics (PK): Area Under the Concentration Versus Time Curve (AUC) of Tirzepatide in Part C	Area under the concentration versus time curve during 1 dosing interval (AUC [0-τ]) of Tirzepatide in Part C. τ equals 168 hours.	Predose, 8hours(h), 24h,48h,72h, 168h postdose
Pharmacodynamics (PD): Ratio of AUC of Glucose on Day 2 to Baseline (Part C)	PD: Glucose area under the concentration versus time curve from time 0 to 2 hours (AUC[0-2h]) in Part C. Ratio to Baseline (Day -1) AUC (0-2h).	Pre-glucose dose, 0.5, 1, 1.5, 2 hours post-glucose dose on Day -1 and Day 2
Pharmacodynamics (PD): Ratio of AUC of Glucose on Day 23 to Baseline (Part C)	PD: Glucose area under the concentration versus time curve from time 0 to 2 hours (AUC[0-2h]) in Part C. Ratio to Baseline (Day -1) AUC (0-2h).	Pre-glucose dose, 0.5, 1, 1.5, 2 hours post-glucose dose on Day -1 and Day 23

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

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 Eastern time (UTC/GMT -5 hours, EST), Eli Lilly and Company

Publications

From PubMed

These publications come from PubMed, a public database of scientific and medical articles. This list is automatically created by ClinicalTrials.gov Identifier (NCT Number), and these articles may or may not be about the study.

- Coskun T, Sloop KW, Loghin C, Alsina-Fernandez J, Urva S, Bokvist KB, Cui X, Briere DA, Cabrera O, Roell WC, Kuchibhotla U, Moyers JS, Benson CT, Gimeno RE, D'Alessio DA, Haupt A. LY3298176, a novel dual GIP and GLP-1 receptor agonist for the treatment of type 2 diabetes mellitus: From discovery to clinical proof of concept. Mol Metab. 2018 Dec;18:3-14. doi: 10.1016/j.molmet.2018.09.009. Epub 2018 Oct 3.

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Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates	Results Reporting Dates	Study Record Updates
First Submitted	**Results First Submitted**	**Last Update Submitted that met QC Criteria**
2016-04-29	2022-06-09	2023-04-17
First Submitted that Met QC Criteria	**Results First Submitted that Met QC Criteria**	**Last Update Posted**
2016-04-29	2023-04-17	2024-01-16
First Posted (Estimated)	**Results First Posted**	**Last Verified**
2016-05-03	2024-01-16	2023-04

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Record History

Expand all / Collapse all

Terms related to this study

Additional Relevant MeSH Terms

Glucose Metabolism Disorders
Metabolic Diseases
Endocrine System Diseases
Diabetes Mellitus
Diabetes Mellitus, Type 2
Incretins
Hormones
Hormones, Hormone Substitutes, and Hormone
Antagonists
Physiological Effects of Drugs
Glucagon-Like Peptide-1 Receptor Agonists
Hypoglycemic Agents
Dulaglutide
Tirzepatide

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

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Tirzepatide

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Yes

IPD Plan Description

Anonymized individual patient level data will be provided in a secure access environment upon approval of a research proposal and a signed data sharing agreement.

IPD Sharing Access Criteria

A research proposal must be approved by an independent review panel and researchers must sign a data sharing agreement.

IPD Sharing Time Frame

Data are available 6 months after the primary publication and approval of the indication studied in the US and EU, whichever is later. Data will be indefinitely available for requesting.

IPD Sharing Supporting Information Type

Study Protocol
Statistical Analysis Plan (SAP)
Clinical Study Report (CSR)

IPD Sharing Url

http://vivli.org/

Drug and device information, study documents, and helpful links

Study Documents Provided by Eli Lilly and Company

- Study Protocol [PDF, 0.72MB, 2017-02-06]
- Statistical Analysis Plan [PDF, 0.43MB, 2016-05-04]

Helpful Links Provided by Eli Lilly and Company

Click here for more information about this study:A Study of tirzepatide in Participants With Type 2 Diabetes (T2DM)

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Ex. 2009-009