Predicting Long-Term Outcome Risk with Tirzepatide: A Post-Hoc Analysis of SURMOUNT-1

First published: 05/12/2022

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Study Planned

Administrative details

EU PAS number

EUPAS49988

Study ID

49989

DARWIN EU® study

No

Study countries

☐ United States

Study description

This study will evaluate the change in predicted risk for cardiovascular disease and type 2 diabetes between tirzepatide and placebo-treated participants using the SURMOUNT-1 trial data at baseline and 72 weeks. SURMOUNT-1 was a phase 3 trial in adults with overweight or obesity evaluating the impact of tirzepatide versus placebo on weight loss and associated endpoints. The predicted risk will be calculated using validated risk engines.

Study status

Planned

Research institutions and networks

Institutions

Eli Lilly and Company

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Lilly Value Evidence and Outcomes
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Study contact

emily.hankosky@lilly.com

Primary lead investigator

Lilly Value Evidence and Outcomes

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/07/2022

Actual: 27/06/2022

Study start date

Planned: 09/12/2022

Data analysis start date

Planned: 09/12/2022

Date of final study report

Planned: 31/01/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

2022-11193_S-1 Risk Prediction_Protocol_EXPERT response_v2_clean_amended (1).pdf(687.35 KB)

2022-11193_S-1 Risk Prediction_Protocol_EXPERT response_v3_clean.pdf (767.53 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

Pangaea ID 2022-11193

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To describe and compare the change from baseline predicted risk of long-term outcomes (listed below) between tirzepatide and placebo at 72 weeks among people with overweight or obesity using SURMOUNT-1 trial data. -Atherosclerotic Cardiovascular Disease -Type 2 diabetes

Study drug and medical condition

Medical condition to be studied

Obesity

Type 2 diabetes mellitus

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

2500

Study design details

Outcomes

Predicted risk for cardiovascular disease and predicted risk for type 2 diabetes

Data analysis plan

The primary analysis will use the American College of Cardiology/American Heart Association (ACC/AHA) risk engine to calculate CVD risk scores and the Cardiometabolic Disease Staging (CMDS) engine to calculate T2D risk scores. Risk scores will be calculated at baseline and Week 24 and Week 72 as well as the change of risk score from baseline.

Documents

Study publications

Jastreboff AM, Aronne LJ, Ahmad NN et al. Tirzepatide Once Weekly for the Treat...

Data management

Data sources

Data source(s), other

SURMOUNT-1 trial United States

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No