Weight regain after completion of SURMOUNT-CN trial: The SURMOUNT-CN trial follow-up study (SURMOUNT-CN follow-up study)

First published: 08/03/2023

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/105087

EU PAS number

EUPAS103493

Study ID

105087

DARWIN EU® study

No

Study countries

China

Study description

This is a real-world observational study with primary data collection and secondary data use. This follow-up study will enroll patients who completed the SURMOUNT-CN trial, with a planned follow-up duration of 26 weeks. The aim of this follow-up study is to examine changes in body weight and waist circumferences in 26 weeks at 13-weekly intervals from treatment cessation among those who completed SURMOUNT-CN trial in real-world practice settings in China. No investigational medicine is applied in this follow-up study. The follow-up data will be provided by patients, whereas study baseline data (at trial randomization, week 52 and week 56) will be derived from SURMOUNT-CN trial via patient-level data linkage.

Study status

Ongoing

Research institutions and networks

Institutions

ZhongShan Hospital

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Institution

Contact details

Study institution contact

Lilly China Value Evidence and Outcomes

Study contact

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Primary lead investigator

Lilly China Value Evidence and Outcomes

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 27/10/2022

Study start date

Planned: 28/04/2023

Actual: 19/04/2023

Date of final study report

Planned: 29/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and company

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 number:2022-11868

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To examine the change in body weight by treatment arms from week 52 to week 56, week 65 and to week 78 following discontinuation of SURMOUNT-CN study treatment. To examine the change in waist circumferences by treatment arms from week 52 to week 56, week 65 and to week 78 following

discontinuation of SURMOUNT-CN treatment.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Overweight

Obesity

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

190

Study design details

Outcomes

The absolute and relative change in body weight, the absolute change in waist circumferences

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Data analysis plan

Descriptive statistics will be used to summarise study outcomes only among eligible analysis population. For continuous variables, mean and standard deviations (SD) or median and range (minimum, maximum) will be summarized. Frequencies and proportions will be reported for categorical variables. In addition, if data permit, regression analysis will be used to test the association between the weight change starting from treatment discontinuation at week 52 and variables of interest (e.g. randomized treatment, weight loss during trial period, etc.), while adjusting for selected covariates from general characteristics. Clinical indicators of interest will be defined as protocol-defined AEs and summarized by cut-off values as per Chinese clinical guidelines. The numbers of patients with protocol-defined AE categories (by low, high) at week 52, week56, week 65 and week 78 will be summarized by SURMOUNT-CN study treatment arms.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, SURMOUNT-CN trial for baseline data extraction

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