

# 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

**Last updated:** 02/07/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS103493

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### Study ID

105087

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### DARWIN EU® study

No

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### Study countries

 China

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### 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.

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### **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 ssi@lilly.com

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

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**Study start date**

Planned: 28/04/2023

Actual: 19/04/2023

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**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

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## 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

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#### **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)

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### **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

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

### Data sources

## **Data sources (types)**

Other

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### **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## **Data characterisation**

### **Data characterisation conducted**

No