

# A Post-Marketing Safety Study of Mounjaro® (Tirzepatide) in Chinese Participants who are Overweight or have Obesity with or without Type 2 Diabetes Mellitus in a Real-World Setting

**First published:** 28/01/2025

**Last updated:** 28/01/2025

Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000461

### Study ID

1000000461

### DARWIN EU® study

No

### Study countries

☐ China

## Study description

This is a single-country, single arm, prospective, non-interventional study among Chinese participants who are overweight or have obesity with newly administered tirzepatide in a real-world clinical setting. This is a new user design study that identifies participants who initiate tirzepatide and begins follow-up after the initiation of the treatment. The observation period for each case will be either up to 24 weeks from the initial administration of tirzepatide or until discontinuation of the study, whichever comes first. The incidence of AEs and SAEs will be described.

This PMSS is also designed to describe the demographics, clinical characteristics and treatment patterns, as well as effectiveness on weight management and improvement of comorbidities in participants with overweight or obesity newly treated with tirzepatide.

---

## Study status

Planned

## Contact details

### Study institution contact

YU DONG [dong\\_yu1@lilly.com](mailto:dong_yu1@lilly.com)

Study contact

[dong\\_yu1@lilly.com](mailto:dong_yu1@lilly.com)

### Primary lead investigator

Xiao Ying Li

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 27/01/2025

Actual: 27/01/2025

---

**Study start date**

Planned: 29/08/2025

---

**Data analysis start date**

Planned: 09/05/2028

---

**Date of final study report**

Planned: 09/08/2028

## Sources of funding

- Pharmaceutical company and other private sector

## Regulatory

**Was the study required by a regulatory body?**

Yes

---

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

---

**Study design:**

This is a single-country, single arm, prospective, non-interventional study among Chinese overweight or obese participants with or without T2DM who are newly administered tirzepatide in real-world clinical setting.

**Main study objective:**

The primary objective is to describe the incidence of all adverse events (AEs) including SAEs among participants newly treated with at least 1 dose of tirzepatide during a maximum of 24 weeks of follow up from the initial administration of tirzepatide in real-world clinical practice in China.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

MOUNJARO

---

**Study drug International non-proprietary name (INN) or common name**

TIRZEPATIDE

---

**Anatomical Therapeutic Chemical (ATC) code**

(A10BX16) tirzepatide

tirzepatide

## Population studied

**Short description of the study population**

The study population includes overweight or obese Chinese adult participants ( $\geq 18$  years of age) with or without T2DM and newly treated with tirzepatide. Tirzepatide will be prescribed in a real-world clinical setting and administered according to the usual practices of the treating physicians.

## Study design details

**Setting**

This is a single-country, single arm, prospective, non-interventional study among Chinese overweight or obese participants with or without T2DM who are newly administered tirzepatide in real-world clinical setting. This is a study that identifies participants who initiate tirzepatide and begin follow-up after the initiation of the treatment. The observation period for each case will be either up to 24 weeks from the initial administration of tirzepatide or until discontinuation of the study (e.g., participants discontinue tirzepatide before 24

weeks, participants withdraw their consent of the study, loss of follow up), whichever comes first. Based on collected AE and SAE data, the incidence of AEs and SAEs will be described. The relatedness to administration of tirzepatide will be determined by the investigator.

This PMSS is also designed to describe the demographics, clinical characteristics and treatment patterns as well as effectiveness on weight management and comorbidities improvement in participants with overweight or obesity newly treated with tirzepatide.

---

### **Comparators**

N/A

## 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.

## 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**

Not applicable