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

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000461

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

Study contact

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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 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

Name of medicine

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 (≥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

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