Tirzepatide (Mounjaro®) Benefit for EArly glycemic and weight managemenT in patients with type 2 diabetes vs. oral semaglutide (Rybelsus®) in real world setting – the T BEAT study (2023-12154)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/106060

EU PAS number

EUPAS106059

Study ID

106060

DARWIN EU® study

No

Study countries

Japan

Study description

Primary objective: - To compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by HbA1c change from baseline after up to 12 months of treatment. Key secondary objective: - To compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by body weight change and percent change from baseline after up to 12 months of treatment. Other secondary objectives: - To compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by the proportion of participants achieving HbA1c targets (<5.7%, <6%, ≤6.5%, <7%) after up to 12 months of treatment. - To compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by the proportion of participants who achieve weight loss targets (≥3%, ≥5%, ≥10%, ≥15%) after up to 12 months of treatment. - To compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by metabolic parameters (waist circumference, blood pressure, serum lipids, liver function, and fasting plasma glucose FPG) after up to 12 months of treatment. - To compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by treatment satisfaction (Diabetes Treatment Satisfaction Questionnaire change version DTSQc) after up to 12 months of treatment. - To compare the treatment persistency of tirzepatide vs. oral semaglutide over up to 12 months of treatment.

Study status

Planned

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Contact details

Study institution contact

Manaka Sato

Study contact

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Primary lead investigator

Manaka Sato

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/08/2023

Study start date

Planned: 15/12/2023

Date of final study report

Planned: 31/12/2025

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Eli Lilly Japan K.K., Mitsubishi Tanabe Pharma Corporation

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Drug utilisation

Main study objective:

The main objective is to compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by HbA1c and body weight change from baseline after up to 12 months of treatment.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10BX16) tirzepatide

tirzepatide

(A10BJ06) semaglutide

semaglutide

Medical condition to be studied

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

540

Study design details

Outcomes

Primary objective is to compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by HbA1c change from baseline after up to 12 months of treatment. Key secondary objective is to compare the real-world effectiveness of tirzepatide vs. oral semaglutide as measured by body weight change and percent change from baseline after up to 12 months of treatment.

Data analysis plan

In the efficacy estimand analysis, change from baseline in HbA1c after up to 12 months of treatment will be analyzed for the EAS using a MMRM with index treatment, visit, treatment by visit interaction, and baseline variables with imbalance remaining after performing IPTW despite being used for the PS model as fixed effects. In the ITT estimand analysis, change from baseline in HbA1c after up to 12 months of treatment will be analyzed for the FAS using an ANCOVA model with index treatment and baseline variables with imbalance remaining after performing IPTW despite being used for the PS model as covariates. Missing values for HbA1c at the 12-month evaluation point will be imputed based on participants who discontinued index therapy or initiated some rescue medication before or at 12 months and whose HbA1c values at the 12-month evaluation point are available (‘retrieve dropout’).

Data management

Data sources

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