Body weight and waist circumference change in midlife women treated with tirzepatide by menopausal status: an observational study in UK primary care

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Study Planned

Administrative details

EU PAS number

EUPAS1000000983

Study ID

1000000983

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This study aims to examine the change in weight-related and cardiometabolic features after initiation of tirzepatide (TZP) for management of overweight and obesity in midlife women (40–60 years old) resident in the UK, according to their baseline menopause status (pre-, peri- and post-menopausal). The study will consist of a retrospective, longitudinal cohort study in the UK primary care setting, using data from the Optimum Patient Care Research Database (OPCRD). Characteristics at the time of TZP initiation (baseline) will be reported, including clinical and sociodemographic features. The main outcomes of interest are change in body weight, waist circumference, waist/height index and cardiometabolic risk markers (including blood pressure and lipid profiles) at month 6 and 12 after TZP initiation. The proportion of women achieving different weight reduction targets will also be reported.

Study status

Planned

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Costello Medical Ltd

Contact details

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Study timelines

Date when funding contract was signed

Planned: 28/05/2025

Actual: 28/05/2025

Study start date

Planned: 01/10/2026

Date of final study report

Planned: 01/02/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Study funded by 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

Anonymised Data Ethics & Protocol Transparency Committee (ADEPT) Protocol Reference: PROTOCOL2372;

ADEPT Approval Reference: ADEPT0626

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

The study will consist of a retrospective, longitudinal cohort study in the UK primary care setting, using data from the Optimum Patient Care Research Database (OPCRD).

Main study objective:

Primary objectives:

1. To investigate cardiometabolic and weight-related features, medications, and socio-demographic characteristics at baseline (date of first TZP initiation in primary care), stratified by baseline menopausal status (pre-, peri- and post-menopause)
2. To investigate change from baseline in weight-related outcomes and cardiometabolic risk markers at month 6 and 12 following initiation of TZP, stratified by baseline menopausal status (pre-, peri- and post-menopause)

Secondary objectives:

1. To describe TZP utilisation patterns stratified by baseline menopausal status (pre-, peri- and post-menopause), including dosing (additionally stratified by

baseline glucose tolerance [normal, prediabetes and T2D]) and persistence
2. To describe prevalence of concomitant medication use (including antidiabetic drugs, antihypertensive drugs and lipid-lowering drugs) at baseline and over follow-up, stratified by baseline menopausal status (pre-, peri- and post-menopause)

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

Medical condition to be studied

Obesity

Overweight

Population studied

Short description of the study population

The study population consists of midlife women (40–60 years old) with obesity or overweight who newly initiate TZP in UK clinical practice between 1 Jan 2025–31 Mar 2026 in the Optimum Patient Care Research Database (OPCRD).

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)

Study design details

Setting

The study will consider midlife (40–60-year-old) women with obesity or overweight who newly initiate TZP in UK clinical practice between 1 Jan 2025–31 Mar 2026.

The following inclusion criteria will apply:

1. Sex recorded as female
2. Initiation of TZP treatment during 1 Jan 2025–31 Mar 2026
3. Aged 40–60 years at index date (date of TZP initiation)
4. Eligibility to receive TZP for overweight or obesity according to its marketing authorisation, either:

a. Obesity (body mass index [BMI] ≥30), recorded within 18 months before index date, OR

b. Overweight (27≤BMI<30), recorded within 18 months before index date, and ≥1 diagnosis with a weight-related comorbidity

The following exclusion criteria will apply:
1. Less than 18 months of clinical data available prior to TZP initiation
2. Prescription for TZP or other incretin weight loss medication at any time prior to index
3. Surgical weight-loss treatment at any time prior to index
4. Weight loss of >5kg in the 3 months prior to index
5. Dosage for the index prescription of TZP greater than 2.5mg
6. Premature menopause (before age 40) recorded prior to index, whether occurring naturally or induced.

Stratification by baseline menopausal status will be considered throughout the study, with women categorised into one of three groups according to an algorithm based on age, clinical codes and prescription data: pre-menopausal, peri-menopausal, post-menopausal.

Outcomes
All outcomes will be reported by baseline menopausal status (pre-, peri- and post-menopause).

Primary outcomes:
1. Baseline characteristics (socio-demographic characteristics, weight-related and cardiometabolic features [see below], obesity-related comorbidities, medications)
2. Change from baseline to months 6 and 12 in weight-related and cardiometabolic features (weight, waist circumference, waist/height index, total cholesterol, high density lipoprotein [HDL] cholesterol, low density lipoprotein [LDL] cholesterol, triglycerides, systolic blood pressure, diastolic blood pressure, haemoglobin A1c [HbA1c])

Secondary outcomes:

1. TZP utilisation patterns (dosage at 3, 6, 9, 12 months; persistence)

2. Prevalence of other medication use at months 3, 6, 9 and 12 of follow-up (antidiabetic, antihypertensive and lipid-lowering drugs)

Data analysis plan

Descriptive summary statistics will include:

• For categorical variables: number, number missing, frequency, and percentage (with the denominator excluding the number missing).

• For continuous variables: number, number missing, mean, median, interquartile-range, standard deviation, standard error, and range

Results will be presented overall and as stratified by menopause group. Change from baseline in the clinical and cardiometabolic outcomes to month 6 and 12 will be analysed using one-sample t-tests to test whether the mean absolute change in the measures is different from zero. An analysis of variance (ANOVA) will be used to test whether the mean change from baseline differs significantly between menopause groups.If the change from baseline is non-normally distributed, the Wilcoxon signed-rank test will be used to test whether the change from baseline is symmetric around zerothe Kruskall Wallis or paired Mann Whitney U test will be applied to assess whether the distribution of change from baseline varies between menopause groups.

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 source(s)

Optimum Patient Care Research Database

Data sources (types)

Electronic healthcare records (EHR)

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

Unknown