I8F-MC-B016 Tirzepatide Pregnancy Registry - A Multi-Country Registry-Based Observational Study to Assess Maternal, Fetal, and Infant Outcomes Following Treatment with Tirzepatide for Weight Management During Pregnancy

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Study Planned

Administrative details

EU PAS number

EUPAS1000000517

Study ID

1000000517

DARWIN EU® study

No

Study countries

Germany

United Kingdom

United States

Study status

Planned

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sangmi Kim

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/03/2024

Actual: 29/03/2024

Study start date

Planned: 30/06/2025

Date of final study report

Planned: 30/06/2036

Study protocol

LY3298176 Zepbound Pregnancy Registry Study B016 Protocol v5_Redacted (1).pdf (1.3 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Study design:

The Tirzepatide Pregnancy Registry study is a multi-country, prospective, observational cohort study designed to evaluate the association between tirzepatide exposure during pregnancy and subsequent maternal, fetal, and infant outcomes.

Main study objective:

The aim of the Tirzepatide Pregnancy Registry study is to compare the maternal, fetal, and infant outcomes of individuals treated with tirzepatide for weight management during pregnancy (tirzepatide exposed cohort) with outcomes in two comparator cohorts:

- Anti-obesity medication [AOM] active comparator cohort: Individuals who are treated with pharmacotherapy other than tirzepatide or other therapies with GLP-1 receptor agonist (GLP-1 RA) activity for weight management during pregnancy
- AOM unexposed comparator cohort: Individuals who have obesity or are overweight with at least one weight
related comorbid condition at the time of conception; and who are not treated with tirzepatide, GLP-1 RA
therapies, or any products for weight management during pregnancy

The primary objective is to describe and compare the overall prevalence of major congenital malformations (MCM) among individuals treated with tirzepatide for weight management during pregnancy relative to the two comparator cohorts of pregnant individuals (AOM active comparator cohort and AOM unexposed comparator cohort).

The secondary objective is to describe and compare the prevalence of maternal pregnancy complications, fetal and infant outcomes other than MCM, and postnatal growth and development outcomes between pregnant individuals

treated with tirzepatide for weight management during pregnancy and the two comparator cohorts of pregnant individuals (AOM active comparator cohort and AOM unexposed comparator cohort). The secondary outcomes of interest are as follows:

Maternal pregnancy complications

- Gestational diabetes
- Pregnancy-induced hypertension
- Pre-eclampsia
- Eclampsia

Fetal outcomes

- Spontaneous abortion (SAB)
- Induced abortion
- Stillbirth

Infant outcomes

- Minor congenital malformations
- Preterm birth
- Small for gestational age (SGA)

Postnatal growth and development outcomes

- Postnatal growth deficiency (up to one year of age)
- Infant developmental delay (up to one year of age)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

TIRZEPATIDE

Anatomical Therapeutic Chemical (ATC) code

(A10BX16) tirzepatide

tirzepatide

Population studied

Special population of interest

Pregnant women

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)

Pregnancy registry

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