TAK-555-5002: Observational Study to Assess Maternal and Fetal Outcomes Following Exposure to Prucalopride during Pregnancy

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45769

EU PAS number

EUPAS41866

Study ID

45769

DARWIN EU® study

No

Study countries

United States

Study description

This study will collect information on pregnant women diagnosed with constipation from their health care insurance claims records. It will include the following groups: - Those who took prucalopride. - Those who took other medicines for constipation. - Those who did not take any prescription medicines for constipation. The main aim of the study is to assess the risk of major birth defects with the mother’s use of prucalopride during the first 3 months of pregnancy. The study uses existing health care insurance information, participants are not enrolled, treated, or required to visit the doctor during this study.

Study status

Ongoing

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Study Contact Takeda

Study contact

TrialDisclosures@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 31/05/2019

Study start date

Actual: 01/01/2022

Data analysis start date

Planned: 01/03/2026

Date of final study report

Planned: 30/06/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

The objective is to study to assess risk of major congenital malformations in relation to first trimester exposure to prucalopride.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prescription event monitoring, case-series

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A06AX05) prucalopride

prucalopride

Medical condition to be studied

Constipation

Population studied

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Estimated number of subjects

100

Study design details

Outcomes

Percentage of Infants With Major Congenital Malformations, 1.Percentage of Participants With Spontaneous Abortions 2.Percentage of Participants With Stillbirths 3.Percentage of Participants With Preterm Delivery 4.Percentage of Infants With Small for Gestational Age 5.Percentage of Infants With Neonatal Intensive Care Unit Admission

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Data analysis plan

Source population and different subcohorts of interest (i.e. women with constipation on different treatment strategies) will be characterized. Patterns of constipation medications throughout pregnancy will be described to understand utilization.The primary analysis will estimate the relative risk of pre-specified outcomes for pregnancies exposed to prucalopride compared to other laxatives or no exposure to any prescription medications for constipation.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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