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

First published: 15/07/2021

Last updated: 04/12/2025

Study Ongoing

Administrative details

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 the two large 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 find out whether the medicine prucalopride, which is used to treat constipation, is safe for use during pregnancy and to look at whether taking prucalopride at certain times during pregnancy is associated to a higher chance of specific health problems for the mother or baby. The study uses two large existing health care insurance databases for collecting information, participants are not enrolled, treated, or required to visit the doctor during this study.

Study status

Ongoing

Research institutions and networks

Institutions

Takeda

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Study Contact Takeda TrialDisclosures@takeda.com

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: 01/01/2027

Date of final study report
Planned: 31/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

TAK-555-5002 Protocol V3.0_redacted.pdf (553.73 KB)

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:

Drug utilisation

Safety study (incl. comparative)

Main study objective:

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

Study Design

Non-interventional study design

Cohort

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 Terminations (Discontinuation of Pregnancy) 3. Percentage of Participants With

Stillbirths 4. Percentage of Participants With Preterm Delivery 5.Percentage of Infants With Small for Gestational Age 6. Percentage of Infants With Neonatal Intensive Care Unit Admission. 7. Percentage of Infants With Hospitalizations 8. Percentage of Participants With Poor Growth and Developmental Delays or Disorders.

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 constipation drugs or no exposure to any prescription medications for constipation.

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)

Administrative healthcare records (e.g., claims)

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