

# 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.

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## 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](mailto:TrialDisclosures@takeda.com)

**Primary lead investigator**

Study Contact Takeda

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 31/05/2019

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**Study start date**

Actual: 01/01/2022

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**Data analysis start date**

Planned: 01/01/2027

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**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

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### **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

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##### **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

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### Medical condition to be studied

Constipation

## Population studied

### Age groups

- Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
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### 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.

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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 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

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

### Data characterisation conducted

No