TAK-555-5001: Prucalopride Pregnancy Exposure Study: A VAMPSS Post-Marketing Surveillance of Prucalopride Safety in Pregnancy

First published: 16/04/2021

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48262

EU PAS number

EUPAS40231

Study ID

48262

DARWIN EU® study

No

Study countries

United States

Study description

This study collects information on pregnant women with ongoing constipation who took prucalopride and those who did not take prucalopride. The main aim of the study is to learn if any medical problems in pregnant women or their infants might be related to taking prucalopride during their pregnancy.

Study status

Ongoing

Research institutions and networks

Institutions

Organization of Teratology Information Specialists (OTIS)

First published: 01/02/2024

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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: 01/06/2019

Study start date

Actual: 21/05/2021

Data analysis start date

Planned: 19/12/2025

Date of final study report

Planned: 26/06/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

TAK-555-5001 Protocol V4.0_redacted.pdf(1.54 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

Other study registration identification numbers and links

ClinicalTrials.gov: NCT04869280

Study information

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The objective is to evaluate the potential effect of exposure to prucalopride in pregnancy compared with a group of disease-matched pregnant women who are not exposed 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

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

616

Study design details

Outcomes

Major Structural Defects in Children, 1. Number of Participants With Spontaneous Abortion/Miscarriage 2. Number of Participants With Stillbirth 3. Number of Participants With Elective Termination/Abortion 4. Number of Participants With Premature Delivery 5. Small for Gestational Age 6. Postnatal Growth Deficiency of Live Born Children 7. Screening for Neurodevelopmental Milestones 8. Hospitalization in Live Born Children

Data analysis plan

Major structural defects in children will be analyzed. The primary comparison will be the birth prevalence of major structural defects between exposed group and unexposed group among pregnancies resulting in at least one live born infant.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Exposure 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