TAK-555-4006: A Breast Milk Study in Lactating Women Who Have Been Prescribed Therapeutic Doses of MOTEGRITY® (prucalopride) for Chronic Idiopathic Constipation to Evaluate Prucalopride Concentrations in Breast Milk, and to Collect Incidental Safety Data from the Nursing Infant

First published: 25/03/2021

Last updated: 22/01/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48470

EU PAS number

EUPAS40105

Study ID

48470

DARWIN EU® study

No

Study countries

☐ United States

Study description

Prucalopride is a medicine used to treat constipation. The main aim of the study is to measure prucalopride concentrations in breast milk. Other aims are to collect information on the growth and development of infants whose mothers took prucalopride while breastfeeding and to monitor the infant for medication side effects.

Study status

Ongoing

Research institutions and networks

Institutions

UC San Diego Human Milk Research Biorepository

First published: 01/02/2024

Last updated: 01/02/2024

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: 19/09/2019

Study start date

Actual: 02/03/2022

Data analysis start date

Planned: 31/10/2027

Date of final study report

Planned: 30/04/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

TAK-555-4006 Protocol V1.1_redacted.pdf(2.5 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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Other

If ‘other’, further details on the scope of the study

Pharmacokinetic study

Main study objective:

The main objective of the study is to measure prucalopride concentrations in breast milk.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Pharmacokinetic study

Study drug and medical condition

Name of medicine, other

MOTEGRITY

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

PRUCALOPRIDE SUCCINATE

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)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

12

Study design details

Outcomes

1. Area Under the Milk Concentration-time Curve (AUCmilk) of Prucalopride 2. Average Concentration of Prucalopride in Milk 3. Area Under the Milk Concentration-time Curve from Time 0 to Time t Over the Dosing Interval,
1. Number of Infants With Adverse Events (AEs) Based on Maternal Report 2. Change in Growth (Length and Weight) During the First Year of Life in Infants 3. Infant’s Neurodevelopmental Performance Based on Ages and Stages Questionnaire-3 (ASQ-3)

Data analysis plan

Primary outcomes, i.e. pharmacokinetic parameters, will be determined from the breast milk concentration-time data for prucalopride by noncompartmental analysis using actual sampling times. Summary statistics will be determined for all PK parameters. The secondary endpoints of the study are maternal report of infant AEs, growth and performance on development questionnaires. All secondary endpoints will be summarized using descriptive statistics. Means and SDs will be presented for continuous variables and frequencies and percentages will be presented for categorical variables. Associations between drug levels and infant outcomes will be explored.

Data management

Data sources

Data sources (types)

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