A Prospective, Registry-based, Observational Study to Assess Maternal, Fetal and Infant Outcomes Following Exposure to Rimegepant: The Migraine Observational Nurtec Pregnancy Registry (MONITOR)

First published: 26/01/2022

Last updated: 26/11/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS45356

Study ID

45357

DARWIN EU® study

No

Study countries

United States

Study description

This observational exposure registry will compare the occurrence of major congenital malformations in the fetuses/infants of women with migraine exposed to rimegepant during pregnancy or just prior to pregnancy to those not exposure to rimegepant during or just prior to pregnancy.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Pharmaceutical Product Development (PPD)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

ANDREA LEAPLEY ANDREA.LEAPLEY@PFIZER.COM

Study contact

ANDREA.LEAPLEY@PFIZER.COM

Primary lead investigator

Sarah MacDonald 0000-0001-8790-7243

Primary lead investigator

ORCID number:

0000-0001-8790-7243

Study timelines

Date when funding contract was signed

Planned: 09/11/2020

Actual: 09/11/2020

Study start date

Planned: 01/07/2021

Actual: 23/09/2021

Data analysis start date

Planned: 01/04/2034

Date of interim report, if expected

Planned: 15/04/2022

Date of final study report

Planned: 01/04/2035

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

PFIZER 100%

Study protocol

C4951005_MONITOR PROTOCOL CLEAN_V1.0_18AUG2021.pdf (581.92 KB)

C4951005_MONITOR PROTOCOL CLEAN_V7.0_11AUG2025.pdf (729.83 KB)
C4951005_MONITOR PROTOCOL CLEAN_V6.0_05FEB2025.pdf (703.44 KB)
C4951005_MONITOR PROTOCOL CLEAN_V2.0_08NOV2022.pdf (745.02 KB)
C4951005_MONITOR PROTOCOL CLEAN_V3.0_25APR2023.pdf (1.3 MB)
C4951005_MONITOR PROTOCOL CLEAN_V4.0_27FEB2024.pdf (716.9 KB)
C4951005_MONITOR PROTOCOL CLEAN_V5.0_18OCT2024.pdf (688.86 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

This study is a prospective, observational, pregnancy exposure registry of pregnant women with migraine who were exposed to rimegepant in the US conducted using primary data collection.

Main study objective:

To compare the occurrence of major congenital malformations (MCMs) in the fetuses/infants of women with migraine who were exposed to rimegepant during pregnancy or just prior to pregnancy (up to 3 days prior to conception) with:

1) an internal cohort of women with migraine who were not exposed to rimegepant during pregnancy or just prior to pregnancy (up to 5 product half-lives prior to conception) and

2) an external cohort of pregnant women without migraine.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Nurtec ODT

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

RIMEGEPANT

Anatomical Therapeutic Chemical (ATC) code

(N02CD06) rimegepant

rimegepant

Medical condition to be studied

Migraine

Population studied

Short description of the study population

The study population includes pregnant women with migraine who were exposed to rimegepant in the United States.

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

780

Study design details

Setting

This study is US-based. The study became open for enrollment on 23 September 2021.

The data collection process for each participant will begin at enrollment, with data collection from the participant and her HCP.

For prospectively enrolled participants, follow-up with the maternal HCP will occur at the end of the second trimester (approximately 26 gestational weeks) and/or in the month of estimated date of delivery (EDD) for pregnancy outcome (delivery or early termination).

The second trimester pregnancy follow-up may not be applicable for women who enroll late in pregnancy.

If a live birth is reported, the registry will conduct follow-up with the infant's HCP at 4 and 12 months after delivery.

At approximately 4 months after delivery, infant data at 2 and 4 months of age will be collected; at approximately 12 months after delivery, infant data at 6 and 12 months of age will be collected.

An annual interim study report, reviewed by the Scientific Advisory Committee (SAC), has been submitted to the Center for Drug Evaluation and Research (CDER) beginning April 2022. The Interim Report summarizes the status and the cumulative data that are current to the most recent annual data cutoff period. The estimated end of data collection is April 2034, and a final study report will be submitted by April 2035.

The internal study population will include pregnant women of any age within the US with migraine who were treated with rimegepant as part of routine care at any time during pregnancy or just prior to pregnancy (up to 3 days prior to conception), as well as pregnant women with migraine who were not exposed to rimegepant during pregnancy or just prior to pregnancy (up to 5 product half-lives prior to conception).
Eligible pregnant women may self-enroll or voluntarily be enrolled by their HCP. Enrollment should occur as early in pregnancy as possible.

Enrollment and data collection will be coordinated through the Registry Coordinating Center (RCC).

Comparators
The registry will include 2 comparator groups:

Pregnant women with migraine who are unexposed to rimegepant cohort: migraine diagnosis and no exposure to rimegepant before or during the pregnancy period. Women in this cohort may or may not be exposed to other migraine therapies during pregnancy.

Pregnant women without migraine cohort: 1) external published US background outcome rates among pregnant women without a diagnosis of migraine, 2) the

comparison population of the retrospective pregnancy outcomes study (NDA 212728, post-marketing requirement 3799-7, Pfizer study C4951006 [formerly BHV3000-403]) as an additional resource for non-migraine comparison group outcome rates of MCM, SAB, elective termination, stillbirth, pre-eclampsia/eclampsia, preterm birth, and SGA. Women in this cohort may or may not be exposed to medications during pregnancy.

This study will also use external published and population-based data on migraine to provide context for any events observed in the cohort of pregnant women with migraine who were exposed to rimegepant and the cohort of pregnant women with migraine who were unexposed to rimegepant.

Outcomes

The primary objective is to compare the rate of major congenital malformations in the fetuses/infants of women with migraine exposed to rimegepant (during pregnancy or just prior to pregnancy) to women with migraine not exposed to rimegepant before or during pregnancy and pregnant women without migraine. The secondary objective is to compare the rate of adverse fetal outcomes, maternal pregnancy complications, infant outcomes at birth, and infant events of interest up to 1 year post-delivery in women with migraine exposed to rimegepant during pregnancy or just prior to pregnancy, as well as in women with migraine not exposed to rimegepant before or during pregnancy and pregnant women without migraine

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Data analysis plan

Descriptive analyses for the primary and secondary study objectives will be performed annually for all data; comparative analyses will be conducted for the final analysis.

Registry data will be summarized in tables and listings by study cohort, as

appropriate. These data include maternal demographic characteristics and pre-pregnancy anthropometrics, pregnancy information, maternal obstetrical history, family history of congenital malformations, disease information, maternal exposures during pregnancy, pregnancy outcome information, and infant outcome information.
For each continuous variable, the number of observations, median, mean, standard deviation, minimum, and maximum will be reported. For each categorical variable, the frequency and percentage in each category will be reported.
The frequency and percentage of participants with missing data for each data point will be presented. Results will be rounded to one decimal place; therefore, percentages may not always add up to 100.

Pair-wise comparisons of demographic characteristics, baseline characteristics, and prevalence rates of the outcomes of interest will be conducted between the study cohorts: pregnant women with migraine who were exposed to rimegepant versus pregnant women with migraine who were unexposed to rimegepant.

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 source(s)

Other data source

Data source(s), other

Migraine Observational Nurtec Pregnancy Registry (MONITOR)

Data sources (types)

Pregnancy 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