Retrospective Cohort Study of Pregnancy Outcomes in Women Exposed to Rimegepant During Pregnancy

First published: 24/02/2022

Last updated: 17/06/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS45952

Study ID

45953

DARWIN EU® study

No

Study countries

United States

Study description

The purpose of the study is to evaluate the risk of pregnancy and infant outcomes among women with migraine exposed to rimegepant during pregnancy and in two rimegepant unexposed comparator groups, one of pregnant women with migraine treated with other medications indicated for the acute treatment or prevention of migraine during pregnancy, and a group of pregnant women without migraine.
This is an observational, retrospective, cohort study using prospectively collected secondary health care data from two US data sources.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Optum

Germany

First published: 03/01/2012

Last updated: 07/02/2014

Institution | Outdated | Other | ENCePP partner

RTI Health Solutions (RTI-HS)

France
Spain
Sweden
United Kingdom
United Kingdom (Northern Ireland)
United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

Carelon Research

Contact details

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Study contact

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Primary lead investigator

Sarah MacDonald

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 18/06/2020

Actual: 18/06/2020

Study start date
Planned: 15/12/2021

Actual: 11/08/2021

Date of interim report, if expected
Planned: 29/04/2022

Actual: 29/04/2022

Date of final study report
Planned: 30/04/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer (100%)

Study protocol

C4951006_PROTOCOL_V1.0_08DEC2021_unsigned.pdf (1.3 MB)

C4951006_PROTOCOL_V8.0_27NOV2025.pdf (2.14 MB)
C4951006_PROTOCOL_V7.0_10DEC2024.pdf (1.82 MB)
C4951006_PROTOCOL_V6.0_23FEB2024.pdf (1.71 MB)
C4951006_PROTOCOL_V5.0_21AUG2023.pdf (1.6 MB)
C4951006_PROTOCOL_V4.0_17APR2023.pdf (1.78 MB)
C4951006_PROTOCOL_V3.0_08NOV2022.pdf (1.85 MB)
C4951006_PROTOCOL_V2.0_05AUG2022.pdf (6.84 MB)

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)

Other study registration identification numbers and links

NCT05198245

https://www.medpagetoday.com/clinical-trial-finder/study/nct05198245

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This is an observational, retrospective, cohort study using two health care data sources of prospectively collected secondary data.
The source population will be pregnant women and their children born during the study period.

Main study objective:

The primary objective is to evaluate the risk of pregnancy and infant outcomes with major congenital malformations (MCMs) as the primary outcome of interest, and other primary outcomes including spontaneous abortions, fetal deaths/stillbirths, and small for gestational age (SGA) births among women with migraine exposed to rimegepant during pregnancy and in 2 rimegepant-unexposed comparator groups.

Specific objectives are as follows:

• Objective 1: To describe patterns of use of rimegepant and other medications

for migraine in pregnant women with migraine.
• Objective 2: To estimate the frequency of pregnancy outcomes (i.e., spontaneous abortions, fetal deaths/stillbirths, elective terminations), complications of pregnancy (i.e., preeclampsia/eclampsia), and fetal/infant outcomes (i.e., MCMs, SGA births, and preterm births) in women with migraine exposed to rimegepant during pregnancy and in 2 comparator groups of pregnant women not exposed to rimegepant
• Objective 3: To estimate the adjusted relative risks (RRs) for the study outcomes among women exposed to rimegepant in pregnancy compared with the unexposed comparator groups.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

VYDURA

Medicinal product name, other

Nurtec ODT

Vydura

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 source for the study population will consist of women who have been pregnant during the study period in the selected US data source. Pregnant women will have to fulfill the following eligibility criteria:

• Has a pregnancy code or a recorded pregnancy outcome (i.e., live birth, stillbirth, spontaneous abortion, or elective termination) within the study observation period

• Be aged 16 to 49 years, inclusive, at the estimated LMP within the study observation period.

In this population of pregnant women, we aim to identify 3 study groups:

• Pregnant women with migraine treated with rimegepant

• Pregnant women with migraine, unexposed to rimegepant, treated with other migraine medications

• Pregnant women without migraine, unexposed to rimegepant

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

8064

Study design details

Setting

This study will be conducted in two US health care claims data sources.

Comparators

The primary comparator group will include pregnancies in women with migraine exposed to medications for the treatment of migraine other than rimegepant.
Inclusion criteria:
• Have a migraine diagnosis that meets the criteria in Protocol Table 4 any time before the estimated LMP and through whichever is first: end of pregnancy or end of the study period
• Have at least 1 pharmacy dispensing for a medication indicated for the treatment of migraine within the 30-day time window before the estimated LMP and ending with whichever is first: end of pregnancy or end of the study period. Medications indicated for the treatment of migraine include NSAIDs, acetaminophen, triptans, ergots, opioids, betablockers, anti-epileptics, antidepressants, and botulinum toxin
• Have a recorded outcome of pregnancy within the study period

• Had continuous enrollment in a health care plan with medical and pharmacy benefits during the 6-month period before the estimated LMP through a postpartum period of 42 days
Exclusion criterion:
• Have at least 1 pharmacy dispensing for rimegepant within the 30-day time window before the estimated LMP and through whichever is first: end of pregnancy or end of the study period

The secondary comparator group will include rimegepant-unexposed pregnancies in women without migraine.
Inclusion criteria:
• Have no migraine diagnosis that meets the criteria in Protocol Table 4 any time before the estimated LMP through whichever is first: end of pregnancy or end of the study period
• Have a recorded outcome of pregnancy within the study period
• Had continuous enrollment in a health care plan with medical and pharmacy benefits during the 6-month period before the estimated LMP through a postpartum period of 42 days
Exclusion criterion:
• Have at least 1 pharmacy dispensing for rimegepant within the 30-day time window before the estimated LMP through whichever is first: end of pregnancy or end of the study period.

Outcomes
The primary outcome of interest is:
• Major congenital malformations

Other primary outcomes are the following:
• Spontaneous abortions

• Fetal deaths/stillbirths
• Small for gestational age births

The secondary outcomes are the following:
• Elective terminations
• Pre-eclampsia or eclampsia (combined), during pregnancy and through the postpartum period
• Preterm births.

Data analysis plan
A drug utilization analysis of use of rimegepant and other migraine medications will include number of users and mean, standard deviation, median, IQR of number of dispensings, and number of days between consecutive dispensings for each medication group.
A description of the cohort attrition, selected characteristics of pregnancies in each exposure group, and frequency of study outcomes will be reported for each study group.
For the safety comparative analyses, if feasible, the study groups will be matched on propensity scores to control for confounding and channeling.
Each woman in the rimegepant-exposed group will be matched in a 1:n variable-matching ratio with up to 3 women in each of the comparator groups (separately). Regression models will be used to compare pregnant women with migraine exposed to rimegepant with women in the primary comparator group and in the secondary comparator group.
Point estimates and 95% CIs from analyses within the matched study groups will be presented.

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

Optum Research Database- United States

Carelon Research HIRD- United States

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

Unknown