Observational study of exposure to baricitinib during pregnancy in US-based administrative claims data (I4V-MC-B036)

First published: 12/12/2023

Last updated: 21/02/2025

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49807

EU PAS number

EUPAS49806

Study ID

49807

DARWIN EU® study

No

Study countries

☐ United States

Study description

The objective of this observational study is to evaluate the safety of baricitinib in pregnancy women and their linked infants. In addition to describing clinical and demographic characteristics of pregnancy women with evidence of exposure to baricitinib during pregnancy, this study will describe the following outcomes among the women and their linked infants, and compare the occurence of these outcomes to a similar cohort of unexposed pregnancy women and their infants: - major congenital malformations - recognized spontaneous abortions - stillbirths - small for gestational age - preterm birth

Study status

Planned

Research institutions and networks

Institutions

Aetion

Spain

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Last updated: 16/07/2024

Institution | Other | ENCePP partner

Contact details

Study institution contact

Kristin Meyers

Study contact

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Primary lead investigator

Kristin Meyers

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 17/10/2022

Actual: 17/10/2022

Study start date
Planned: 30/06/2024

Date of final study report
Planned: 28/06/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

LY3009104 B036 NI PASS Protocol V2_ENCePP_Redacted.pdf(475.25 KB)

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:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The 1st objective is to describe demographic and clinical characteristics of pregnant women with evidence of exposure to baricitinib during pregnancy, and to summarize occurrence of the prespecified adverse pregnancy outcomes. The 2nd objective is to estimate the RR of the outcomes among pregnant women with a diagnosis of AA and a dispensing of baricitinib compared to similar women without JAK exposure

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

OLUMIANT

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

BARICITINIB

Anatomical Therapeutic Chemical (ATC) code

(L04AF02) baricitinib

baricitinib

Population studied

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Special population of interest

Pregnant women

Estimated number of subjects

868

Study design details

Outcomes

Major congenital malformations, recognized spontaneous abortions stillbirth small for gestational age preterm birth

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Data analysis plan

The primary objective will be achieved through descriptive statistics. Secondary objective of relative risk will be assessed using propensity score methods to adjust for potential confounding.

Data management

Data sources

Data source(s), other

HealthVerity MOM 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

No