Registry based observational study to assess pregnancy and infant outcomes following exposure to baricitinib in pregnancy (I4V-MC-B035)

First published: 05/12/2022

Last updated: 20/10/2026

Study Planned

Administrative details

EU PAS number

EUPAS49999

Study ID

50000

DARWIN EU® study

No

Study countries

United States

Study status

Planned

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Contact details

Study institution contact

Conan Donnelly conan.donnelly@lilly.com

Study contact

conan.donnelly@lilly.com

Primary lead investigator

Conan Donnelly

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/06/2023

Actual: 12/06/2023

Study start date

Planned: 30/06/2024

Date of interim report, if expected
Planned: 30/06/2028

Date of final study report
Planned: 30/06/2034

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

LY3009104 B035 Non-interventional PASS Protocol v3.0_HMA-EMA_Redacted.pdf (792.6 KB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
Not applicable

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:

Primary data collection

Study design:

Prospective cohort study

Main study objective:

The primary objective is to estimate the relative birth prevalence of major congenital malformations at up to 12 months of age among infants born to women with alopecia areata who are exposed to baricitinib during the first trimester as compared to similar women with AA who are unexposed to a JAK inhibitor at any time during pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

OLUMIANT

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

BARICITINIB

Medical condition to be studied

Alopecia areata

Rheumatoid arthritis

Population studied

Short description of the study population

pregnant women from the US

Age groups

- 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

370

Study design details

Setting

US pregnancy exposure registry

Comparators

Women with AA that are unexposed to a JAKi during pregnancy.

Outcomes

Major congenital malformations, minor congenital malformations, recognizzed spontaneous abortions stillbrirths, elective terminations, small for gestational age, preterm birth, effects on postnatal group and development through the first year of life

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Data analysis plan

Descriptive statistics of all participating women and prevalence of all study outcomes will be summarized, overall and by exposure cohort. Propensity score methods will be applied to estimate the relative birth prevalence of outcomes among pregnant women (and infants) with AA exposed to baricitinib during pregnancy compared to similar women with AA whoa re unexposed to a JAKi during pregnancy.

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 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