

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

**First published:** 05/12/2022

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Study

Planned

## Administrative details

### EU PAS number

EUPAS49999

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### Study ID

50000

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study status

Planned

## Research institutions and networks

# Institutions

## Eli Lilly and Company

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

Kristin Meyers meyers\_kristin\_joy@lilly.com

Study contact

[meyers\\_kristin\\_joy@lilly.com](mailto:meyers_kristin_joy@lilly.com)

### Primary lead investigator

Kristin Meyers

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 30/06/2023

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### Study start date

Planned: 30/06/2024

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## **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

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**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

## Population studied

**Age groups**

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

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**Special population of interest**

Pregnant women

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**Estimated number of subjects**

370

## Study design details

## Outcomes

Major congenital malformations, minor congenital malformations, recognized spontaneous abortions stillbirths, elective terminations, small for gestational age, preterm birth, effects on postnatal growth 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 who are 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)

[Other](#)

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## **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No