Pregnancy Exposures and Outcomes in Women with Inflammatory Bowel Disease Treated with Risankizumab: A Cohort Study Utilizing Large Electronic Healthcare Databases with Mother-Baby Linkage in the United States

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000283

Study ID

1000000283

DARWIN EU® study

No

Study countries

United States

Study status

Ongoing

Contact details

Study institution contact

Clinical Trial Disclosures CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Susan Andrade

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/07/2022

Study start date

Actual: 07/04/2025

Data analysis start date

Actual: 07/04/2025

Date of final study report

Planned: 30/06/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

P23-653_Risa_IBD_Pregnancy_Abstractv2.1_13Feb26_Redacted.pdf (337.16 KB)

P23-653_Protocol v2.0_Abstract_Redacted.pdf (102.6 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)

Other study registration identification numbers and links

P23-653

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study topic, other:

Inflammatory Bowel Disease

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

The study will be a population-based, non-interventional, cohort study of pregnant women with moderate-to-severe Inflammatory Bowel Disease (IBD). The primary comparison will be among women with moderate-to-severe IBD exposed to risankizumab versus those exposed to the comparator treatment group.

Main study objective:

The study aim is to evaluate the safety of risankizumab during pregnancy in women with moderate-to-severe IBD. The outcomes of this cohort study are major congenital malformations (MCMs) of the infant among live birth pregnancies, Pregnancy outcomes: live birth, spontaneous abortion, elective abortion, stillbirth and Infant outcomes: premature birth, small for gestational age (SGA), neonatal deaths, serious infections.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

SKYRIZI

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

RISANKIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AC18) risankizumab

risankizumab

Medical condition to be studied

Inflammatory bowel disease

Population studied

Short description of the study population

The study population will include pregnant women (ages 15 to 55 years at the start of pregnancy) diagnosed with IBD and exposed to a medication (biologic or non-biologic) used in the treatment of IBD.

Age groups

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

Special population of interest

Pregnant women

Estimated number of subjects

600

Study design details

Comparators

Population including pregnant women with moderate-to-severe IBD exposed to comparator biologics, including anti-tumor necrosis factor (TNF), integrin receptor antagonist biologics or their biosimilars (comparator biologic-exposed group).

Outcomes

The primary outcome of this cohort study is major congenital malformations (MCMs) of the infant among live birth pregnancies.

Secondary outcomes include the following:

● Pregnancy outcomes: live birth, spontaneous abortion, elective abortion, stillbirth

● Infant outcomes: premature birth, small for gestational age (SGA), neonatal deaths, serious
infections

Data analysis plan

The prevalence (%) of the main outcome (MCMs) and additional outcomes, including other adverse infant outcomes and pregnancy outcomes (live birth, spontaneous abortion, elective abortion, stillbirth), and their 95% confidence intervals (CIs) will be calculated among eligible risankizumab-exposed pregnancies and the corresponding matched comparator biologic-exposed

pregnancies.

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)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes