Pregnancy Exposures and Outcomes in Women with Crohn's 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 Planned

Administrative details

EU PAS number

EUPAS1000000283

Study ID

1000000283

DARWIN EU® study

No

Study countries

☐ United States

Study status

Planned

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

Planned: 30/09/2025

Date of final study report

Planned: 30/06/2033

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

P23653_Risa_CD_pregnancy_abstract_Redacted.pdf(202.89 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

Study topic, other:

Crohn's 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 Crohn's disease (CD. The primary comparison will be among women with moderate-to-severe CD exposed to risankizumab versus those exposed to the comparator treatment group during pregnancy.

Main study objective:

The study aim is to evaluate the safety of risankizumab during pregnancy in women with moderate-to-severe CD. 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

Name of medicine

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

Crohn's disease

Population studied

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

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

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

No