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

First published: 16/03/2021

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS39775

Study ID

47188

DARWIN EU® study

No

Study countries

☐ United States

Study description

The study aim is to evaluate the safety of risankizumab during pregnancy in women with psoriasis.

Study status

Ongoing

Research institutions and networks

Institutions

Reagan-Udall Foundation

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Clinical Trial Disclosure AbbVie

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/05/2021

Actual: 01/07/2021

Study start date
Planned: 31/01/2022

Actual: 21/03/2022

Date of final study report
Planned: 31/10/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

p16751-protocol-pmos abstract-18oct2020_Redacted.pdf(177.15 KB)

riskmgtsystem-pam-p16751-protocol-pmos_v1.4_abstract_Redacted.pdf(150.93 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

P16-751

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The study aim is to evaluate the safety of risankizumab during pregnancy in women with psoriasis.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

SKYRIZI

Medical condition to be studied

Psoriasis

Population studied

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

600

Study design details

Outcomes

The primary outcome of this cohort study is major congenital malformations 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

This study will estimate the incidence (cumulative risks) of pregnancy outcomes, including live births, spontaneous abortions, elective abortion, and stillbirths and will compare the occurrence of these events among risankizumab-exposed women with those among the matched comparator biologic-exposed women. AbbVie will use a log binomial distribution with robust variance using generalized estimating equations to estimate the effects of exposure (cumulative risk ratios and 95% confidence intervals) to risankizumab.

Data management

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

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No