A Retrospective Cohort Study Using Health Administrative Claims Databases to Assess Adverse Pregnancy and Infant Outcomes in Women with Psoriasis Who Were Exposed to Guselkumab Versus Other Biologic Therapies During Pregnancy. PASS-EMA

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Study Ongoing

Administrative details

EU PAS number

EUPAS30740

Study ID

103402

DARWIN EU® study

No

Study countries

United States

Study description

TREMFYA (guselkumab) pregnancy healthcare database study. PASS-EMA

Study status

Ongoing

Contact details

Study institution contact

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Study contact

RA-RNDUS-ClinclTrlsEU@its.jnj.com

Primary lead investigator

Kevin Haynes

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 13/07/2017

Study start date

Actual: 01/09/2025

Data analysis start date

Planned: 31/12/2022

Actual: 01/02/2023

Date of final study report
Planned: 30/12/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen R&D

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)

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:

To estimate and compare the prevalence of MCM between infants born to women with PsO who were exposed to guselkumab and infants born to women with PsO who were exposed to other biologics during pregnancy, To estimate and compare the risk of a composite adverse pregnancy outcome between women with PsO exposed to guselkumab and women with PsO exposed to other biologics during pregnancy

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

This is a phase 4, observational, retrospective cohort study using electronic health administrative claims databases in the US

Study drug and medical condition

Medicinal product name

TREMFYA

Medical condition to be studied

Psoriasis

Population studied

Age groups

- Adults (18 to < 46 years)

Estimated number of subjects

100

Study design details

Outcomes

Major congenital malformation AND composite adverse outcome of major congenital malformation, spontaneous abortion, stillbirth, small for gestational age, preterm birth, neonatal death combined, Spontaneous abortion, stillbirth, preterm birth, small for gestational age, neonatal death, and infant infections

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Data analysis plan

Descriptive analysis will include maternal characteristics and pregnancy outcomes according to PsO treatment during pregnancy, including guselkumab, other biologics, non-biologics, photo-therapies, or topical alone. The prevalence of the adverse pregnancy outcomes will be estimated as the number of pregnancies ending with these outcomes divided by the number of completed pregnancies at-risk during the study period. A 1:5 matched sample will be constructed based on propensity score (PS) for pregnancy exposure to guselkumab versus other biologics to balance the distribution of potential confounders. The primary analysis will use logistic regression model to estimate

the risk ratio of the adverse pregnancy outcomes associated with maternal exposure to guselkumab during the pre-specified at-risk time windows. For the infant outcome of hospitalized infections up to 1 year of age, a Cox regression model will be conducted.

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

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No