Dupilumab and Pregnancy Outcomes: A Retrospective Cohort Study Using Administrative Healthcare Databases (Dupi PODS)

First published: 14/12/2021

Last updated: 02/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS43837

Study ID

43838

DARWIN EU® study

No

Study countries

☐ United States

Study description

The objective of this study is to describe and compare the incidence of adverse pregnancy outcomes (spontaneous abortion/miscarriage, stillbirth) and prevalence of infant outcomes (major congenital malformations MCMs, small for gestational age SGA) in women with AD who are treated with dupilumab during pregnancy relative to women with AD who are not treated with dupilumab during pregnancy.

Study status

Ongoing

Research institutions and networks

Institutions

Regeneron Pharmaceuticals

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Institution

Contact details

Study institution contact

Study Director Regeneron

clinicaltrialdisclosureteam@regeneron.com

Study contact

clinicaltrialdisclosureteam@regeneron.com

Primary lead investigator

Study Director Regeneron

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 27/03/2018

Study start date
Actual: 30/09/2019

Data analysis start date
Planned: 21/01/2027

Date of final study report
Planned: 26/02/2027

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Regeneron Pharmaceuticals,Inc., Sanofi

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

R668-AD-1760,NCT03936335

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 objective of this study is to describe and compare the incidence of adverse pregnancy outcomes (spontaneous abortion/miscarriage, stillbirth) and prevalence of infant outcomes (major congenital malformations MCMs, small for gestational age SGA) in women with AD who are treated with dupilumab during

pregnancy relative to women with AD who are not treated with dupilumab during pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Dermatitis atopic

Additional medical condition(s)

Adverse Pregnancy Outcomes

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

3930

Study design details

Outcomes

• Incidence of major congenital malformations, • Incidence of spontaneous abortion or miscarriage • Incidence of stillbirth • Incidence of small for gestational age

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Data analysis plan

The analysis aims to characterize and quantify the occurrence of pregnancy outcomes. Descriptive statistics will be reported for the dupilumab exposed group and 1:2 matched comparator groups. Adjusted risk ratios will be estimated for dupilumab exposure groups compared to unexposed groups for the study outcomes.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Medical chart review

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