Post-Authorization Safety Study to Monitor Pregnancy and Infant Outcomes Following Administration of Dupilumab During Planned or Unexpected Pregnancy in North America

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Last updated: 14/03/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/43820

EU PAS number

EUPAS43819

Study ID

43820

DARWIN EU® study

No

Study countries

- [ ] Canada
- [ ] United States

Study description

The objective is to evaluate the potential effect of exposure to dupilumab in pregnancy compared to the primary comparison group of disease-matched pregnant women who are not exposed to dupilumab, and the secondary comparison group of healthy pregnant women. The primary outcome of the study is major structural defects, and the secondary outcomes of the study are spontaneous abortion/miscarriage, stillbirth, elective termination/abortion, premature delivery, small for gestational age, pattern of 3 or more minor structural defects, postnatal growth of live born children to 1 year of age, postnatal serious or opportunistic infections in live born children to 1 year of age, and hospitalizations in live children up to 1 year of age.

Study status

Ongoing

Research institutions and networks

Institutions

Regeneron Pharmaceuticals

First published: 01/02/2024

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Institution

Networks

European Forum for Primary Care (EPFC)

- [ ] Austria
- [ ] Belgium
- [ ] Bulgaria
- [ ] Croatia
- [ ] Cyprus
- [ ] Czechia
- [ ] Denmark
- [ ] Estonia
- [ ] European Union
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Iceland
- [ ] Ireland
- [ ] Italy
- [ ] Latvia
- [ ] Liechtenstein
- [ ] Lithuania
- [ ] Luxembourg
- [ ] Malta
- [ ] Netherlands
- [ ] Norway
- [ ] Poland

- [ ] Portugal
- [ ] Romania
- [ ] Slovakia
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom (Northern Ireland)

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Network ENCePP partner

Organization of Teratology Information Specialists (OTIS) Network

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Network

Contact details

Study institution contact

Study Director Regeneron

Study contact

clinicaltrialdisclosureteam@regeneron.com

Primary lead investigator

Study Director Regeneron

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 11/01/2018

Study start date
Actual: 24/10/2018

Data analysis start date
Planned: 09/01/2026

Date of final study report
Planned: 09/07/2026

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Regeneron, 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-1639,NCT04173442

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 is to evaluate the potential effect of exposure to dupilumab in pregnancy compared to the primary comparison group of disease-matched pregnant women who are not exposed to dupilumab, and the secondary comparison group of healthy pregnant women.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Dermatitis atopic

Asthma

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Pregnant women

Estimated number of subjects

500

Study design details

Outcomes

• Rate of major structural defects, • Incidence of spontaneous abortion or miscarriage and stillbirth • Incidence of elective termination/abortion • Incidence of premature delivery • Incidence of small for gestational age • Incidence of a pattern of 3 or more minor structural defects • Postnatal growth deficiency • Incidence of postnatal serious or opportunistic infections and hosptializations in live born children

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Data analysis plan

The analyses in this study aim to characterize and quantify outcomes of interest. Following descriptive analyses of the study groups, frequencies of outcomes by group and adjusted risk ratios will be calculated to compare dupilumab exposed groups to the non-exposed groups.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Exposure registry

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