The Benralizumab Pregnancy Exposure Study: A VAMPSS Post-Marketing Surveillance Study

First published: 07/11/2018

Last updated: 22/11/2024

Study Finalised

Administrative details

EU PAS number

EUPAS26461

Study ID

45903

DARWIN EU® study

No

Study countries

Canada

United States

Study status

Finalised

Research institutions and networks

Institutions

Organization of Teratology Information Specialists (OTIS)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University California SD

Networks

Organization of Teratology Information Specialists (OTIS) Network

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Christina Chambers

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/12/2017

Actual: 20/12/2017

Study start date

Planned: 01/09/2018

Actual: 20/03/2019

Data analysis start date

Planned: 01/11/2025

Actual: 26/12/2023

Date of interim report, if expected

Planned: 15/12/2019

Actual: 12/12/2018

Date of final study report

Planned: 30/03/2027

Actual: 23/08/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca AB

Study protocol

d3250r00026-csp-v2_Redacted_15Nov2018.pdf (1.26 MB)

d3250r00026-csp-v3_Redacted_27Jul2020(final version).pdf (491.03 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

D3250R00026

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 monitor planned and unplanned pregnancies exposed to benralizumab and evaluate the potential teratogenic effect of this medication relative to the primary pregnancy outcome of major structural birth defects and the secondary pregnancy outcomes of preterm delivery, small for gestational age infants, spontaneous abortion, stillbirth, elective termination and postnatal growth to one year of age.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This is a prospective, observational, exposure cohort study of pregnancy outcomes in pregnant women with asthma exposed to benralizumab and comparison women

Study drug and medical condition

Medicinal product name, other

FasenraTM

Medical condition to be studied

Asthma

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- 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

800

Study design details

Outcomes

Major structural birth defects, - Spontaneous abortion/miscarriage - Stillbirth - Elective termination/abortion - Preterm delivery - Small for gestational age infants - Small for age postnatal growth of live born children to 1 year of age

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Data analysis plan

Descriptive tables will be prepared for characteristics of each of the cohorts in each interim and final report displaying n, means, standard deviations,

minimums and maximums or proportions and percentages. For the primary endpoint and for the secondary endpoints un-adjusted relative risk estimates will be presented together with exact two-sided 95% and 80% confidence intervals. For the secondary endpoints survival methods will be used (Kaplan Meier) to estimate crude rates and confidence intervals accounting for gestational timing of enrollment in the study. Adjusted analyses producing relative risks and 95% and 80% confidence intervals or hazard ratios and 95% and 80% confidence intervals, where numbers permit, will be conducted. Confounders will be considered for each adjusted analysis separately, using several methods including the method of change in estimate of the effect of exposure to benralizumab by 10% or more.

Documents

Study results

OTIS Benralizumab Final Analysis Report_Synopsis_Redacted.pdf (354.46 KB)

Study report

2019 FINAL OTIS BENRALIZUMAB ANNUAL INTERIM REPORT_03Dec2019.pdf (384.32 KB)

2020 OTIS Benralizumab Pregnancy Registry Annual Report_10Nov2020.pdf (450.17 KB)

2021 FINAL OTIS Fasenra Annual Interim Report_08Feb2022.pdf (725.07 KB)

Study, other information

2020 OTIS Benralizumab Pregnancy Registry Annual Report_10Nov2020.pdf (450.17 KB)

2021 FINAL OTIS Fasenra Annual Interim Report_08Feb2022.pdf (725.07 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Medical records

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