The Mepolizumab Pregnancy Exposure Study: a VAMPSS post marketing surveillance study of Mepolizumab safety in pregnancy (200870 NPSS (Nucala Pregnancy Surveillance Study))

First published: 13/06/2016

Last updated: 09/08/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS13772

Study ID

40792

DARWIN EU® study

No

Study countries

Canada

United States

Study description

The Mepolizumab Pregnancy Exposure Study is a prospective, observational, exposure cohort study of pregnancy outcomes in women exposed to mepolizumab during pregnancy compared to pregnancy outcomes in women who have not used mepolizumab during pregnancy but have used other anti-asthmatic medications (treated disease comparison group), and pregnancy outcomes in women exposed to other non-teratogenic agents, (non-disease comparison group). The purpose of the study is to monitor planned and unplanned pregnancies exposed to mepolizumab and to evaluate the possible teratogenic effect of this medication relative to the primary pregnancy outcome of major birth defects and the secondary pregnancy outcomes of preterm delivery, small for gestational age infants and spontaneous abortion or stillbirth. The study is conducted by the Organization of Teratology Information Specialists (OTIS) Research Center located at the University of California, San Diego.

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

Networks

Organization of Teratology Information Specialists (OTIS) Network

First published: 01/02/2024

Last updated: 01/02/2024

Network

American Academy of Asthma, Allergy and Immunology

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/09/2016

Actual: 20/09/2016

Study start date
Planned: 30/09/2016

Actual: 03/11/2016

Date of final study report
Planned: 30/06/2024

Actual: 22/07/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-200870-protocol-redact.pdf (1.18 MB)

gsk-200870-protocol-redact-v02.pdf (6.95 MB)

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:

The objectives of the study are to assess mepolizumab exposure in pregnancy with respect to major birth defects, spontaneous abortion, stillbirth, preterm delivery, and small for gestational age infants.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

MEPOLIZUMAB

Medical condition to be studied

Pregnancy

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

800

Study design details

Outcomes

The primary analysis will be a comparison of the prevalence rate of major structural defects in live born infants between the mepolizumab-exposed cohort and the treated disease cohort. Multivariable analyses will be conducted as numbers permit. The secondary analyses will be comparisons of the prevalence rates of the following outcomes, small for gestational age, preterm delivery, spontaneous abortion and stillbirth between the mepolizumab-exposed cohort and the treated disease cohort. Multivariable analyses will be conducted as numbers permit.

Data analysis plan

For the primary endpoint of major structural defects and for the secondary endpoint of small for gestational age infants, crude comparisons will be made using exact methods to develop relative risk estimates and their 95% confidence intervals. For the secondary endpoints of preterm delivery, spontaneous abortion, and stillbirth, 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 rates and 95% confidence intervals, where numbers permit, will be conducted for major birth defects and small for gestational age infants using logistic regression. Adjusted analyses producing rates and 95% confidence intervals, for preterm delivery, spontaneous abortion and stillbirth, if numbers permit, will be conducted using Cox Proportional Hazards.

Documents

Study report

Clinical Study Report Anonymized 29 Jul 2024.pdf (3.79 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Medical record abstraction

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