

# 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:** 21/05/2024

Study

Ongoing

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/40792>

### 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.

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### Study status

Ongoing

## Research institution and networks

### Institutions

#### Organization of Teratology Information Specialists (OTIS)

**First published:** 01/02/2024

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Institution

### Networks

#### Organization of Teratology Information Specialists (OTIS) Network

**First published:** 01/02/2024

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Network

American Academy of Asthma, Allergy and Immunology

## Contact details

### Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Study contact

[Pharma.CDR@gsk.com](mailto: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

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### Study start date

Planned:

30/09/2016

Actual:

03/11/2016

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### Date of final study report

Planned:

30/06/2024

## 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

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**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

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**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

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**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)

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**Special population of interest**

Pregnant women

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**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.

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**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.

## Data management

### Data sources

## Data sources (types)

Other

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

### Data characterisation conducted

No