Assessment of pregnancy outcomes in patients treated with reslizumab: Active pregnancy surveillance

First published: 11/03/2018

Last updated: 14/02/2019

Study Ongoing

Administrative details

EU PAS number

EUPAS23021

Study ID

28075

DARWIN EU® study

No

Study countries

- Canada
- Germany
- Netherlands
- United Kingdom

Study description

This is a Phase 4, multinational, non-interventional, active pregnancy surveillance study. The study will provide information on pregnancy outcomes in women with asthma treated with reslizumab during pregnancy in routine clinical practice.

Study status

Ongoing

Contact details

Study institution contact

Sigal Kaplan sigalit.kaplan@teva.co.il

Study contact

sigalit.kaplan@teva.co.il

Primary lead investigator

Sigal Kaplan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/03/2018

Study start date

Planned: 14/03/2018

Actual: 14/03/2018

Date of interim report, if expected
Actual: 19/10/2018

Date of final study report
Planned: 14/03/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva Pharmaceutical Ltd.

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:

To examine pregnant women exposed to reslizumab during pregnancy and to evaluate pregnancy outcomes of major birth defects

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Cinqair

Medical condition to be studied

Asthma

Population studied

Age groups

- Adults (18 to < 46 years)

- Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

266

Study design details

Outcomes

The primary outcome is major birth defects in prospective cases of females exposed to reslizumab during pregnancy. The secondary outcomes are pre-term birth, stillbirth, and spontaneous abortion.

Data analysis plan

The proportion of major birth defects of prospective cases and 95% confidence interval (CI0 will be calculated. Prevalence rates of all secondary endpoints with 95% CIs around the estimated rates will be calculated for pre-term birth, spontaneous abortions, and stillbirth.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency

but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Patient support program

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