Meta-Analysis Plan for Study Number 201182, GSK1550188, SLE, Pregnancy Analysis

First published: 26/10/2015

Last updated: 03/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11405

Study ID

50499

DARWIN EU® study

No

Study countries

☐ United Kingdom

☐ United States

Study description

The purpose of the study is to evaluate maternal, fetal and infant outcome data for subjects with systemic lupus erythematosus (SLE) who were exposed to belimumab during pregnancy. This is an aggregate analysis of pregnancy outcomes and relevant clinical data from the belimumab clinical trials pulling together data from the clinical trial and safety databases up to 08 March 2014.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

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: 15/12/2014

Actual: 15/12/2014

Study start date

Planned: 15/05/2015

Actual: 29/01/2015

Date of final study report

Planned: 15/11/2015

Actual: 19/11/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-201182-reporting-and-analysis-plan-redact.pdf(610.07 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)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To evaluate maternal, fetal and infant outcome data for subjects with systemic lupus erythematosus (SLE) who were exposed to belimumab during pregnancy.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

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

BELIMUMAB

Additional medical condition(s)

SLE and pregnancy

Population studied

Short description of the study population

Adults subjects diagnosed with systemic lupus erythematosus (SLE) who become pregnant while exposed to belimumab during phase 2-4 clinical trials.
Inclusion criteria:
- All cases involving a pregnant patients are included.

Exclusion criteria:
- Cases involving females over 60 years of age and adult males (where the case was not reported as a partner pregnancy) has been excluded.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Immunocompromised

Other

Pregnant women

Special population of interest, other

Patients with systemic lupus erythematosus

Estimated number of subjects

85

Study design details

Outcomes

The primary objective is to determine if there is an increase in birth defects in infants born to women with SLE who were exposed to belimumab during pregnancy. Secondary outcomes include adverse maternal and infant outcomes, e.g. spontaneous miscarriage, preterm birth and still birth.

Data analysis plan

All data will be summarized using descriptive statistics. Continuous variables will be summarized by number of participants, mean, standard deviation, median, lower quartile, upper quartile, minimum and maximum unless otherwise stated. Categorical variables will be summarized by number and percentage in each category. Missing data will be displayed as a separate category where appropriate. The denominator for all percentages will reflect the number of participants within the cohort, unless otherwise stated (e.g. excluding lost to follow-up (LTF)). For primary endpoint birth defects and secondary endpoints (pregnancy outcomes: live birth, neonatal death, stillbirth, spontaneous miscarriage, elective termination, ectopic pregnancy, and molar

pregnancy) prevalence rates and 95% confidence intervals will be summarized.

Documents

Study results

gsk-201182-clinical-study-report-redact.pdf(1.29 MB)

Study publications

Petri M, Landy H, Clowse ME, Gemzoe K, Khamashta M, Kurtinecz M, Levy RA, Liu A...

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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