An observational follow-up study of women who become pregnant while participating in a certolizumab pegol (CZP) clinical study or whose pregnancies have otherwise been reported to UCB due to potential CZP exposure during pregnancy

First published: 27/09/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS11321

Study ID

27134

DARWIN EU® study

No

Study countries

Canada

France

Germany

United States

Study description

The purpose of this observational follow-up study is to collect data systematically on pregnancies and offspring in women who become pregnant while participating in a CZP clinical study or whose pregnancies have otherwise been reported to UCB due to potential CZP exposure during pregnancy.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 4 centres are involved in the study

Contact details

Study institution contact

Clinical Trial Registries and Results Personal identifiable data of lead investigator are not published here, as consent according to Section 4a of the German Federal Act on Data

Protection is not available. clinicaltrials@ucb.com

Study contact

clinicaltrials@ucb.com

Primary lead investigator

Clinical Trial Registries and Results Personal identifiable data of lead investigator are not published here, as consent according to Section 4a of the German Federal Act on Data Protection is not available.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/12/2015

Actual: 11/12/2015

Study start date

Planned: 30/12/2016

Actual: 16/11/2016

Date of final study report

Planned: 18/12/2018

Actual: 18/12/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

UCB BIOSCIENCES, Inc.

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

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

Other

If ‘other’, further details on the scope of the study

Pregnancy follow up study

Data collection methods:

Secondary use of data

Main study objective:

The primary objectives for this observational follow-up study are to estimate the risks of major congenital malformations (MCMs) and to evaluate pregnancy outcomes among women who become pregnant while enrolled in a Certolizumab Pegol (CZP) study or whose pregnancies have otherwise been reported to UCB due to potential CZP exposure during pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Axial spondyloarthritis

Ankylosing spondylitis

Rheumatoid arthritis

Crohn's disease

Psoriatic arthropathy

Population studied

Short description of the study population

Women who became pregnant while enrolled in a Certolizumab Pegol (CZP) study or whose pregnancies had otherwise been reported to UCB due to potential CZP exposure during pregnancy.

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

360

Study design details

Outcomes

Percentage of newborns with major congenital malformationsPercentage of pregnancy outcome with major congenital malformations, Numbers of maternal pregnancy-related eventsPercentage of Vaginal and C-section deliveriesGestational age at birthBirth weightSmall Size for gestational agePercentage of AEs in infantsPercentage of infants less than or equal to the 10th percentile for sex and age with respective to weight, height, head circumference, gross/ fine motor skills, language, cognitive/social skills

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Data analysis plan

Descriptive statistics will be performed for all prospectively reported pregnancy cases for which the minimum eligibility criteria are met and for which the outcome of the pregnancy is available. Summary statistics for categorical variables will consist of frequencies and percentages. For continuous variables, descriptive statistics (number of available observations, mean, median, standard deviation, minimum and maximum with percentiles as optional) will be presented.

Documents

Study results

up0019-synopsis.pdf (1.62 MB)

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)

Drug registry

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

Unknown