

A multicenter postmarketing study to evaluate the placental transfer of certolizumab pegol in pregnant women receiving treatment with Cimzia® (certolizumab pegol) (CRIB)

First published: 07/01/2014

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Study

Finalised

Administrative details

EU PAS number

EUPAS5507

Study ID

21694

DARWIN EU® study

No

Study countries



Canada



France

 Netherlands

 Switzerland

 United States

Study description

The primary purpose is to assess whether there is transfer of CZP from pregnant women receiving treatment with Cimzia® across the placenta to infants by evaluating the concentration of CZP in the plasma of infants at birth.

Study status

Finalised

Research institutions and networks

Institutions

1 Chapel Hill, NC, USA, 20 Bern, Switzerland, 11 Scottsdale, AZ, USA, 7 & 3 Los Angeles, CA & Durham, NC, USA, 500 Maastricht, Netherlands, 9 Oklahoma City, OK, USA, 200 & 202 Paris, France, 203 Lille, France, 101 & 102 Salt Lake City, Utah & New York, NY, USA, 103 Houston, TX, USA

Contact details

Study institution contact

Clinical Trial Registries and Results Personal identifiable data of lead investigator are clinicaltrials@ucb.com

Study contact

clinicaltrials@ucb.com

Primary lead investigator

Clinical Trial Registries and Results Personal identifiable data of lead investigator are

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 12/09/2013

Study start date

Planned: 14/01/2014

Actual: 09/01/2014

Data analysis start date

Actual: 21/11/2016

Date of final study report

Planned: 21/11/2017

Actual: 17/02/2017

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:

Clinical trial

If 'other', further details on the scope of the study

Pharmacokinetic study: placental transfer

Main study objective:

To assess whether there is transfer of CZP across the placenta to infants from mothers by evaluating the concentration of CZP in the plasma of infants at birth

Study Design

Clinical trial regulatory scope

Pre-authorisation clinical trial

Clinical trial phase

Human pharmacology (Phase I)

Clinical trial types

Single-arm trial

Study drug and medical condition

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

CERTOLIZUMAB PEGOL

Medical condition to be studied

Spondylitis

Ankylosing spondylitis

Crohn's disease

Psoriatic arthropathy

Rheumatoid arthritis

Population studied

Short description of the study population

Pregnant women who started or decided to continue treatment with certolizumab pegol (CZP) for an approved indication in accordance with their treating physician prior to participating in the study.

Age groups

- Adults (18 to < 46 years)
 - Adults (46 to < 65 years)
-

Special population of interest

Immunocompromised

Pregnant women

Estimated number of subjects

20

Study design details

Outcomes

The plasma concentration of certolizumab pegol (CZP) in the infant at birth, -
The plasma concentration of CZP in the mother at delivery- The ratio of plasma concentration of CZP between the Infant(s) and mother at birth- The plasma concentration of CZP in the umbilical cord(s) at birth- The plasma concentration of anti-CZP antibodies in the mother at delivery- The plasma concentration of anti-CZP antibodies in the umbilical cord(s) at birth

Data analysis plan

The concentration of CZP in the infant at birth will be summarized descriptively using n (number of available measurements), geometric mean, CV, median,

minimum, and maximum for those infants that provide a valid CZP concentration measurement at birth. Secondary variables will be summarized descriptively in a similar manner. Summaries will be based on observed data, and no inferential statistical analysis is planned.

Documents

Study results

[UP0017-synopsis.pdf](#) (572.91 KB)

Study publications

[Mariette X, Förger F, Abraham B, Flynn AD, Moltó A, Flipo RM, Van Tubergen A, S...](#)

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

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