

# A multicenter, postmarketing study to evaluate the concentration of certolizumab pegol in the breast milk of mothers receiving treatment with Cimzia® (certolizumab pegol) (CRADLE)

**First published:** 24/06/2014

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS6785

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### Study ID

16581

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### DARWIN EU® study

No

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### Study countries

Canada

France

- Netherlands
  - Switzerland
  - United States
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### **Study description**

The primary objectives of this study are to assess whether there is transfer of Certolizumab Pegol (CZP) into breast milk of lactating mothers who are receiving an established dosing regimen of CZP by evaluating the concentration of CZP in mature breast milk, and to calculate the daily infant dose of maternal CZP.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

Multiple centres: 15 centres are involved in the study

11, Scottsdale, AZ, USA

7, Los Angeles, CA, USA

1, Chapel Hill, NC, USA

3, Durham, NC, USA

101, Salt Lake City, UT, USA

500 & 501, Maastricht & Rotterdam, Netherlands

20, Bern, Switzerland

102, New York, NY, USA

200, Paris, France

103, Houston, TX, USA

## 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](mailto:clinicaltrials@ucb.com)

**Study contact**

[clinicaltrials@ucb.com](mailto: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**

Actual: 19/12/2013

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**Study start date**

Planned: 26/06/2014

Actual: 08/09/2014

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**Data analysis start date**

Planned: 22/11/2016

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**Date of final study report**

Planned: 10/01/2017

Actual: 17/05/2016

## 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

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

Not applicable

## Methodological aspects

## Study type

**Study topic:**

Disease /health condition  
Human medicinal product

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**Study type:**

Clinical trial

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

Pharmacokinetic study: breast milk transfer

**Main study objective:**

The primary objectives of this study are to assess whether there is transfer of Certolizumab Pegol (CZP) into breast milk of lactating mothers who are receiving an established dosing regimen of CZP by evaluating the concentration of CZP in mature breast milk, and to calculate the daily infant dose of maternal CZP.

## Study Design

**Clinical trial regulatory scope**

Post-authorisation interventional clinical trial

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**Clinical trial phase**

Human pharmacology (Phase I)

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**Clinical trial types**

Low-intervention clinical trial  
Single-arm trial

## Study drug and medical condition

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

CERTOLIZUMAB PEGOL

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### **Medical condition to be studied**

Spondylitis

Ankylosing spondylitis

Crohn's disease

Psoriatic arthropathy

Rheumatoid arthritis

## Population studied

### **Short description of the study population**

Lactating women who were receiving treatment with Certolizumab Pegol (CZP) for an approved indication.

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### **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
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### **Estimated number of subjects**

16

## Study design details

### **Outcomes**

- The concentration of Certolizumab Pegol (CZP) in breast milk on Day 0, 2, 4, 6, 8, 10, 12, 14, and 28 (as applicable)- The calculated daily infant dose of

Certolizumab Pegol (CZP) in breast milk on Day 2, 4, 6, 8, 10, and 12- The calculated daily infant dose of Certolizumab Pegol (CZP) in breast milk and average daily infant dose over the dosing interval on Day 14 and 28 (as applicable)

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### **Data analysis plan**

The concentration of CZP in breast milk will be summarized descriptively using n (number of available measurements), geometric mean, CV, median, minimum, and maximum for all time points where breast milk is collected. A plot of the CZP concentration in breast milk over time will also be presented. The amount of CZP that the infant may potentially consume daily will be calculated on Day 2, Day 4, Day 6, Day 8, Day 10, Day 12, Day 14, and on or about Day 28 (for women on a CZP Q4W dosing regimen) using the following formula: Estimated Daily Infant Dosage (mg/kg/day) =  $C_{\text{milk}} (\text{average}) \times 150\text{mL/kg/day}$  Where  $C_{\text{milk}}$  = drug concentration in breast milk. This is based on the standardized mean milk consumption for a fully breastfed 2-month old infant of 150mL/kg/day.

## Documents

### **Study results**

[up0016-synopsis.pdf](#) (121.01 KB)

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## Data management

## ENCePP Seal

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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

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### 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

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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