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

Study ID

16581

DARWIN EU® study

No

Study countries

Canada

France

Netherlands

Switzerland

United States

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.

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

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
Actual: 19/12/2013

Study start date
Planned: 26/06/2014

Actual: 08/09/2014

Data analysis start date
Planned: 22/11/2016

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

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

Not applicable

Methodological aspects

Study type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Clinical trial

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

Clinical trial phase

Human pharmacology (Phase I)

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

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.

Age groups

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

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)

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) = Cmilk (average) x 150mL/kg/dayWhere Cmilk = 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)

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

No