A MULTICENTER, POSTMARKETING STUDY TO EVALUATE THE CONCENTRATION OF CERTOLIZUMAB PEGOL IN THE BREAST MILK OF MOTHERS RECEIVING TREATMENT WITH CIMZIA® (CERTOLIZUMAB PEGOL) PHASE 1B (CLINICAL PHARMACOLOGY)

Published: 26-05-2014
Last updated: 20-04-2024

The primary objectives of this study are to assess whether there is transfer of CZP into breastmilk of lactating mothers who are receiving an established dosing regimen of CZP by evaluatingthe concentration of CZP in mature breast milk, and to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON41111

Source
ToetsingOnline

Brief title
UP0016

Condition

- Autoimmune disorders
- Pregnancy, labour, delivery and postpartum conditions

Synonym
autoimmune diseases, reumatological diseases

Research involving
Human

Sponsors and support

Primary sponsor: UCB Biosciences Inc.
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: breast milk, Cimzia®, postmarketing, pregnant women

Outcome measures

Primary outcome

- The concentration of CZP in the breast milk of lactating mothers;

- The calculated daily infant dose of CZP in breast milk;

Secondary outcome

- The concentration of total PEG in the breast milk;

- AEs of the mother and infant from time.

Study description

Background summary

Pregnant women with immunological diseases like RA and CD, and their treating physicians,
would benefit from information about the transfer of CZP in breast milk when assessing the
benefit/risk of whether and how to take CZP in their individual
situations.
This study is considered to be a Postauthorization Safety Study (PASS) because it evaluates risks
of a medicinal product used in patient populations for which safety information is limited or
missing. Although this study is noninterventional with regard to CZP

administration, it is
considered interventional due to fact that breast milk being collected.

Study objective

The primary objectives of this study are to assess whether there is transfer of 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 infant daily dose of maternal
CZP. The exploratory objective is to assess the concentration of polyethylene glycol (PEG) in
breast milk.

Study design

This is a multicenter, postmarketing, prospective study evaluating the concentration of
certolizumab pegol (CZP [CDP870, Cimzia®]) in mature breast milk of lactating mothers who
are receiving commercial CZP in accordance with the current approved prescribing information.

Intervention

not applicable.

Study burden and risks

Collection of breast milk and blood sample for TB test.

Risks associated with study procedures:
- Collection of blood sample for TB testing
- Collection of breast milk

Contacts

Public
UCB Biosciences Inc.

Arco Corporate Drive 8010
Raleigh, North Carolina NC 27617
US

Scientific
UCB Biosciences Inc.

Arco Corporate Drive 8010
Raleigh, North Carolina NC 27617
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. An IRB/IEC approved written Informed Consent form for participation of the maternal subject and her infant (for collection of infant demographic and AE data) is signed and dated by the subject. Where applicable, the written Informed Consent form with respect to the infant is also signed and dated by the holder of parental rights as designated by the maternal subject.
2. Subject is considered reliable and capable of adhering to the protocol and visit schedule according to the judgment of the Investigator.
3. Subject is female and at least 18 years of age at the time of providing consent.
4. Subject has delivered term infant(s) (at least 37 weeks gestation).
5. Subject is being treated with CZP per the current approved prescribing information (Appendix 17.1).
6. The decision to treat with CZP or to breastfeed is made independently from and prior to the
subject consenting to participate in this study.
7. Subject agrees to use only the emollient or nipple cream provided by the Sponsor for use during the Sampling Period.
Additional criteria to be confirmed at Visit 2 (just prior to sampling):
8. Subject is at least 6 weeks postpartum.
9. Subject is on an established dosing regimen of CZP (at least the third dose of CZP since starting/restarting CZP).

Exclusion criteria

1. Subject is taking a prohibited medication or has taken a prohibited medication as defined in
Section 7.3.2. Note: any subjects requiring antibiotics must be discussed with the Medical Monitor prior to enrollment.2. Subject has history of chronic alcohol abuse or drug abuse in the last year.
3. In subjects who intend to breastfeed, the infant has any abnormality noted on physical examination that, in the opinion of the Investigator, may jeopardize or compromise the subject*s ability to participate in this study.
4. Subject has any medical, obstetrical or psychiatric condition that, in the opinion of the Investigator, can jeopardize or would compromise the subject*s ability to participate in this study or the outcome of the pregnancy (as applicable). Note: subjects with mastitis infection should not have samples collected until the infection is completely resolved.
5. Subject has history of breast implants, breast augmentation, or breast reduction surgery.
6. Subject has previously participated in this study.
7. Subject has participated in a study of an investigational medicinal product (IMP) (or a medical device) within the previous 30 days or 5 half-lives (whichever is longer) prior to Screening or is currently participating in another study of an IMP (or a medical device) unless the study is UCB UP0017 or a registry study.
8. Subject has received treatment with any biological therapeutic agent, or other anti-TNF agents with the exception of CZP, within 5 half-lives prior to obtaining the first sample.
9. Subject has a positive or indeterminate QuantiFERON®-TB GOLD In Tube test at Screening. In case of indeterminate result, a retest is allowed if time permits; 2 results of indeterminate require exclusion of the subject (see also exclusion criterion 10 - definition of latent tuberculosis [LTB]). Tuberculosis (TB) test results that have been obtained within the previous 60 days prior to Screening (with negative results) are acceptable (QuantiFERON®-TB GOLD or purified protein derivative [PPD] test).
10. Subject with known TB infection, at high risk of acquiring TB infection, or LTB infection.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2014
Enrollment:	2
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	cimzia
Generic name:	certolizumab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	26-05-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-07-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-03-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-09-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2013-004126-28-NL
CCMO	NL48429.056.14