A MULTICENTER POSTMARKETING STUDY TO EVALUATE THE PLACENTAL TRANSFER OF CERTOLIZUMAB PEGOL IN PREGNANT WOMEN RECEIVING TREATMENT WITH CIMZIA® (CERTOLIZUMAB PEGOL)

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

The primary objective of this study is to assess whether there is transfer of CZP across theplacenta to infants from mothers by evaluating the concentration of CZP in the plasma of infants.The secondary and exploratory objectives are to assess the…

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

Summary

ID

NL-OMON40792

Source
ToetsingOnline

Brief title
UP0017

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: Cimzia®, placental transfer, postmarketing, pregnant women

Outcome measures

Primary outcome

The plasma concentration of CZP in the infant at birth

Secondary outcome

-The plasma concentration of CZP in the mother at delivery

-The ratio between plasma concentration of CZP between the infant and mother at

birth

-The plasma concentration of CZP in the umbilical cord 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 at birth

-AEs of both mother and infant from time of informed consent/assent through

Safety

Follow-Up

Study description

Background summary

Pregnant women with immunological diseases like RA and CD, and their treating

physicians,
would benefit from information about the placental transfer of CZP, and possible CZP levels in infants, 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 the blood samples being collected from the infant,
mother, and umbilical cord are not part of routine clinical practice.

Study objective

The primary objective of this study is 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.
The secondary and exploratory objectives are to assess the concentrations of CZP, anti-CZP
antibodies, and polyethylene glycol (PEG) in the 3 sources of blood samples at the time of birth
(infant, mother, and umbilical cord) and in the infants at 4 weeks and 8 weeks after birth.

Study design

This is a multicenter, postmarketing, prospective study evaluating the placental transfer of
certolizumab pegol (CZP [CDP870, Cimzia®]) by measuring the concentration of CZP in the
infant1, mother, and umbilical cord at birth. Additionally, blood samples will be collected from
the infant at Week 4 and Week 8 after birth in order to assess the pharmacokinetics (PK) of CZP
in infants after birth.

Intervention

Not applicable.

Study burden and risks

Additional blood tests mother, infant and cord.

Risks associated with study procedure:
- Collection of blood samples.

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. Subject is >=30 weeks pregnant with a singleton or twins at the time of informed consent/assent.
2. Subject is being treated with CZP at a dose and administration schedule per the locally approved label.
3. Subject started, or decided to start, treatment with CZP independently from and prior to being

recruited for this study and in accordance with the treating physician.
4. Subject expects to receive CZP until at least 35 days prior to expected delivery.
Additional criteria to be confirmed at Visit 2 (delivery):
5. Subject delivers a live born infant at or near term (>=34 weeks gestation).
6. Subject received CZP within 35 days before delivery.

Exclusion criteria

1. 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 11 - definition of latent tuberculosis [LTB]). Tuberculosis (TB) test results that have been obtained within the previous 60 days prior to Screening are acceptable (QuantiFERON®-TB GOLD or purified protein derivative [PPD] test).
2. Subject has known TB infection, at high risk of acquiring TB infection, or latent TB 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):	30-01-2015
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)

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□003812□30-NL
ClinicalTrials.gov	NCT02019602
CCMO	NL48402.056.14