

## STUDY SUMMARY INTENDED FOR EUROPEAN UNION PATIENTS ONLY

**Short study title:** To look at the transfer of certolizumab pegol across the placenta (CRIB)

**Full study title:** A Multicenter, Postmarketing Study to Evaluate the Placental Transfer of Certolizumab Pegol in Pregnant Women Receiving Treatment with Cimzia® (Certolizumab Pegol)

<b>Thank you</b>	UCB would like to thank all of the participants of this clinical study. Participation in clinical studies like this one provides important information for women of childbearing age who are being treated with certolizumab pegol (Cimzia®).
<b>Background</b>	<ul style="list-style-type: none"><li>• A concern of mothers taking medicine during pregnancy is whether the medicine can get into the baby when carrying the baby during pregnancy.</li><li>• Few studies have been done to measure <u>placental transfer</u> of drugs from mothers to babies.</li><li>• This study was done to measure the amount of certolizumab pegol in blood samples from mothers and their babies.</li><li>• A new test that can measure very low concentrations of certolizumab pegol was used in this study. This test can measure certolizumab pegol concentrations that are about 1/1000th of what is usually found in the blood of women taking certolizumab pegol.</li><li>• The study plan did not include looking at the long-term effects of certolizumab pegol. Neither did the plan include looking at whether or not certolizumab pegol helps to improve the health of the mothers.</li></ul>
<b>Purpose of the study</b>	The main purposes of the study were: <ul style="list-style-type: none"><li>• To see if certolizumab pegol is passed from mothers to their babies during the last part of pregnancy. This was done by measuring the amount of certolizumab pegol in blood samples from the mothers and babies.</li><li>• To look at the <u>side effects</u> of certolizumab pegol in women who are pregnant and give birth, and to look at <u>side effects</u> in their babies.</li></ul>
<b>Study participants</b>	<ul style="list-style-type: none"><li>• Some of the requirements to get into the study were that women:<ul style="list-style-type: none"><li>○ Were at least 18 years old.</li><li>○ Were at least 30 weeks pregnant with either 1 or 2 babies.</li><li>○ Were already taking or would start taking certolizumab pegol as told to by their doctors. The participant had to decide to take certolizumab pegol before she thought about being in the study.</li><li>○ Had taken certolizumab pegol within the last 35 days of their pregnancy.</li></ul></li></ul>

- Sixteen mothers were included in the study:
  - They were from 18 to 41 years old. The average age was 31 years.
  - Each gave birth to 1 baby during the study. This means that 16 babies were included in the study.

## Study design and research methodology

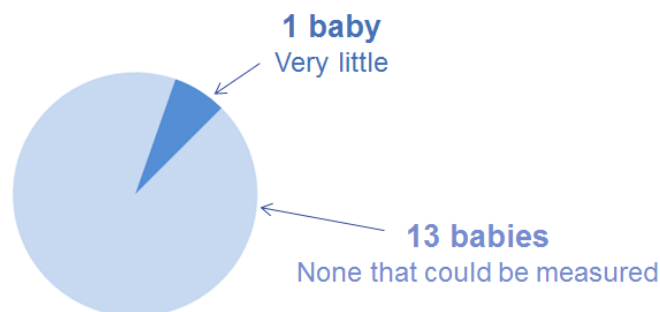
- The study was run in France, the Netherlands, Switzerland, and the US.
- The study started in January 2014 and ended in November 2016.
- Mothers took either 200 milligrams of certolizumab pegol every 2 weeks or 400 milligrams of certolizumab pegol every 4 weeks as told to by their doctors.
- The concentration of certolizumab pegol was measured in blood samples from each:
  - Baby at the time of birth, and 1 month and 2 months after birth.
  - Mother at the time of birth.
- Doctors collected information about participants' medical problems during this study. This was done to look at the safety of the participants and to understand the safety of the study drug. The medical problems that the doctor thought were due to the study drug are called side effects. They are either serious side effects or not serious side effects. The doctor uses a set of rules when deciding whether or not a side effect is serious.

## Key findings

- Very little or no certolizumab pegol was found in the blood of the babies at birth. Specifically,
  - 1 baby had very little certolizumab pegol
  - 13 babies had no certolizumab pegol that could be measured

This same information is shown below in a picture.

Amount of certolizumab pegol found in babies' blood samples at birth



One baby did not have a blood sample collected at birth. There were measurement problems with another baby's sample. This means these two babies could not be included in the information above.

- No certolizumab pegol was found in the blood of any of the babies 1 month and 2 months after their birth. This includes the baby who had a very low concentration of certolizumab pegol in its blood at birth.
- One mother had a serious side effect (perineal abscess) and one baby had a serious side effect (infection). There were no deaths during the study.
- Of the 16 mothers, 3 mothers had side effects. One mother had post-procedural infection. One mother had bacterial vaginosis and urinary tract infection. One mother had perineal abscess (see above) and psoriasis that worsened.
- One baby had a side effect. The side effect was infection (see above). This baby had no certolizumab pegol that could be measured in the blood samples.
- For more information about this study, please visit <https://clinicaltrials.gov/ct2/show/NCT02019602?term=UP0017&rank=1>. For information about other studies for people taking certolizumab pegol, please visit [clinicaltrials.gov](https://clinicaltrials.gov).

**Comment on the outcome of the study**

In this study, very little or no certolizumab pegol could be measured at birth in the blood of babies born to mothers taking certolizumab pegol. No certolizumab pegol could be measured in the babies 1 month and 2 months after birth.

The side effects in the mothers and babies in this study were of the same type as those already known for certolizumab pegol.

The study did not look at long-term effects in mothers who took certolizumab pegol while pregnant or long-term effects in their babies.

**Peer-reviewed publication**

Mariette X, Forger F, Abraham B, Flynn AD, Molto A, Flipo R-M, et al. Lack of placental transfer of certolizumab pegol during pregnancy: results from CRIB, a prospective, postmarketing, pharmacokinetic study. <http://ard.bmj.com/content/early/2017/10/12/annrheumdis-2017-212196> (01 Feb 2018).

Last update on 01 Feb 2018.

*This summary is provided for informational purposes only.*

*This summary only shows the results from this 1 study. Other studies may find different results. The overall results of the study may not reflect the experience of an individual participant of the study. If you need medical advice about your own health or situation, please contact your physician.*

***Thank you again to all participants!!!***