Clinical Study Results

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Study Sponsor:	UCB Biopharma SRL
Treatment Studied:	Certolizumab pegol (CZP)
Protocol Number:	UP0085
Short Study Title:	A study to learn more about the amount of CZP in the blood of pregnant women with chronic inflammatory conditions

Thank you

UCB thanks all the participants of this study. All the participants helped the researchers learn more about how certolizumab pegol acts in the blood of pregnant participants. Certolizumab pegol is often shortened to CZP, and is also called Cimzia®.

This is a summary of the main results of this study. This study is sometimes called the CHERISH study. An independent, non-profit organization helped prepare this summary of the study results, which included feedback from patients.

We think it is important to share the results with the participants and the public. We hope this summary helps the participants understand their important role in medical research.

The purpose of this summary is only to share information. If you need medical advice, please contact your doctor. If you participated in this study and have questions about the results, please speak with study staff.

Overview of this study

Why was the research needed?

Page 3

Researchers are looking for a better way to treat pregnant women with chronic inflammatory conditions. Before a drug is available for all patients, researchers do clinical studies to find out how the drug works and how safe it is.

What treatment did the participants receive?

Page 4

All the participants in this study received CZP. The participants received CZP at their usual dose level from their doctor who normally prescribes it for them outside of the study. The study doctors did not give CZP to the participants.

What were the results of the study?

Page 7

The main questions the researchers wanted to answer in this study were:

- **Did the amount of CZP in the participants' blood change during pregnancy compared to after pregnancy?**
  Yes. Overall, the researchers found that the amount of CZP in the participants' blood decreased during pregnancy compared to after pregnancy. But, the amounts of CZP in the participants' blood **were within the same range** as the amounts of CZP in the blood of people who were not pregnant in other studies.

- **What medical problems did the study doctors report as possibly related to the study treatment?**
  There were 4.8% of participants who had medical problems that the study doctors reported as possibly being related to the study treatment. This was 1 out of 21 participants.

More details about the results of this study are included later in this summary.

Where can I learn more about this study?

Page 10

You can find more information about this study on the websites listed on the last page. If a full report of the study results is available, it can also be found on those websites.

Why was the research needed?

The researchers in this study wanted to learn more about the amounts of CZP in the body during pregnancy and if the participants had any medical problems during the study.

Chronic inflammatory conditions are often life-long medical conditions that happen when the immune system mistakenly attacks the body's own healthy cells. This can cause painful inflammation and many other symptoms that impact daily life depending on the specific condition. These types of diseases are also called **autoimmune diseases**. CZP is a drug that is approved to treat several chronic inflammatory conditions.

Only a small number of studies have looked at the effect of drugs in pregnant women with chronic inflammatory conditions. There is the concern that the drugs may negatively affect an unborn baby. Because of this, women often stop taking certain medications when they become pregnant, even though if they were to keep taking them they may continue to benefit from them without affecting their baby.

By looking at the amount of CZP in the bodies of women during and after pregnancy, researchers can understand how to better treat chronic inflammatory conditions during pregnancy in the future.

What were the main questions studied?

The main questions the researchers wanted to answer in this study were:

- Did the amount of CZP in the participants' blood change during pregnancy compared to after pregnancy?
- What medical problems did the study doctors report as possibly related to the study treatment?

Who participated in the study?

There were 21 pregnant females with chronic inflammatory conditions who participated in this study. They were 24 to 40 years old when they joined.

At first, there were 22 participants who joined the study. But, 1 participant had a miscarriage before receiving any CZP after joining the study. So, that participant is not included in any of the summary information below.

The study included participants in 6 countries:

France	2	Spain	1
Germany	5	Switzerland	4
Netherlands	4	United States	5

In this study, the researchers planned to include pregnant participants living with one of the following chronic inflammatory conditions:

- Rheumatoid arthritis
- Psoriatic arthritis
- Plaque psoriasis
- Crohn's disease
- Axial spondylarthritis (including either ankylosing spondylitis or non-radiographic axial spondylarthritis)

Participants also must have been:

- Less than 10 weeks pregnant when they started the study
- Receiving a stable dose of CZP for at least 12 weeks

Each participant was in the study for up to 58 weeks, but the whole study lasted for a little less than 3 years. The study started in July 2020 and ended in May 2023.

What treatment did the participants receive?

The participants in this study received CZP through an injection under their skin. Doses of CZP were measured in milligrams (mg).

The participants, study doctors, study staff, and UCB staff knew that all the participants in this study were receiving CZP. During the study, the participants received CZP at their usual dose level from their doctor who normally prescribes it for them outside of the study. The study doctors did not give CZP to the participants.

The chart below shows the dose levels of CZP the researchers planned to study:

	Group 1	Group 2	Group 3
	15 participants	1 participant	5 participants
	200 mg of CZP	400 mg of CZP	400 mg of CZP
	Once every 2 weeks	Once every 2 weeks	Once every 4 weeks

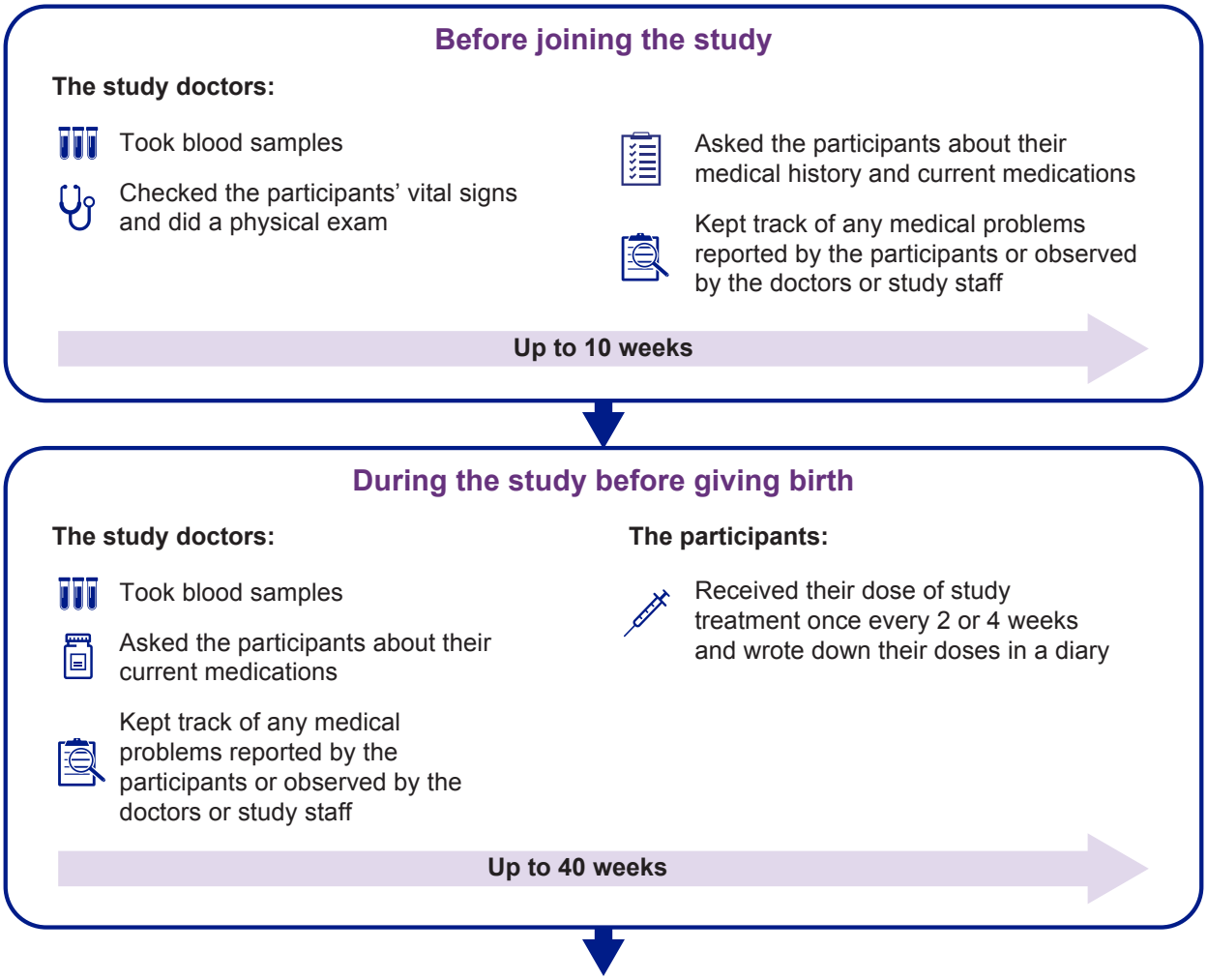
What happened during the study?

This section shows how the study was planned to be done.

Before joining the study, the participants visited their clinic 1 time. All the participants first learned about the study and then decided to join. This is called **informed consent**. Then, the study doctors and study staff asked the participants about their medical history and checked their health to make sure they could join the study. This is called **screening** and it lasted up to 10 weeks.

During the study, the participants had at least 4 in-clinic or at-home study visits so the study doctors could take blood samples. The study doctors also kept track of any medical problems reported by the participants or observed by the doctors or study staff.

The chart below shows how the study was planned to be done:



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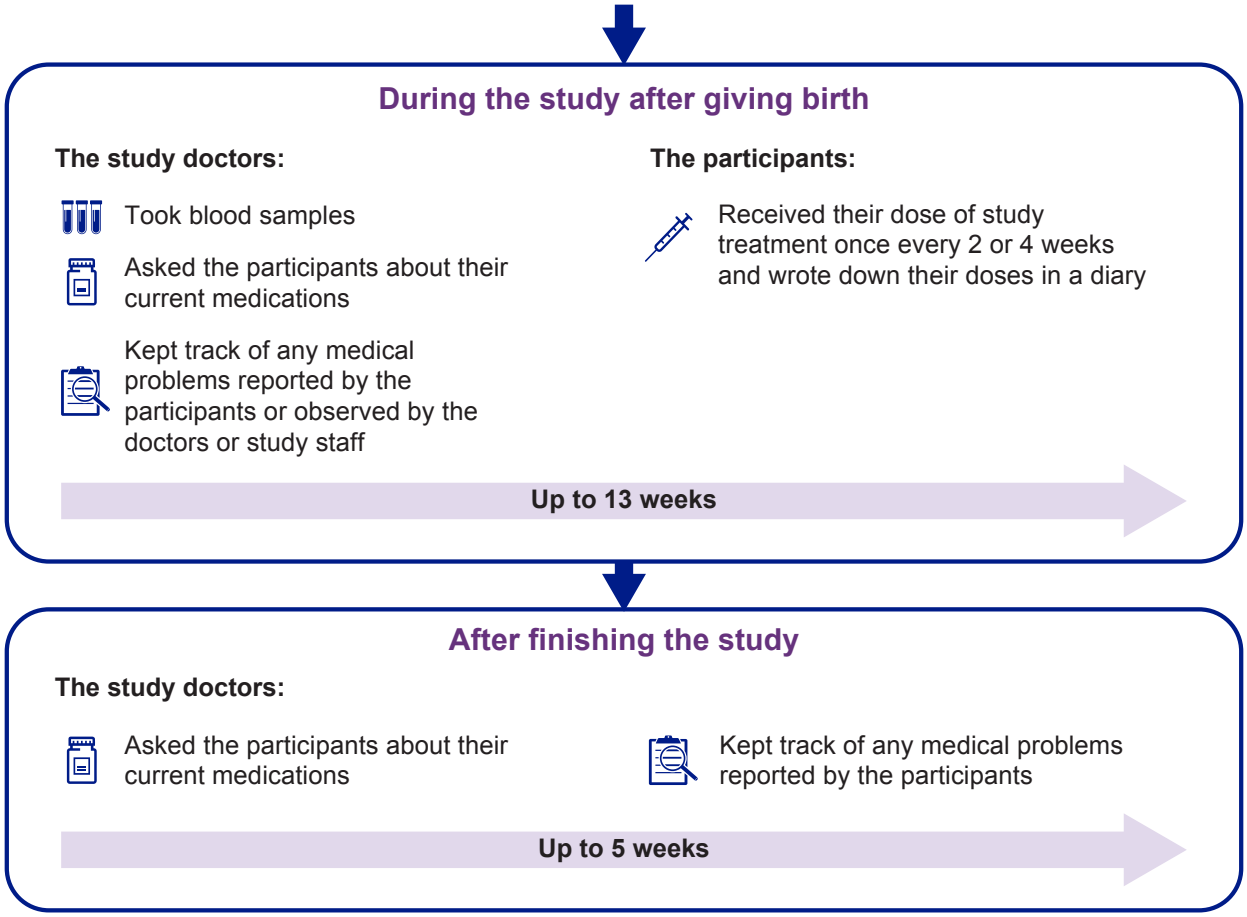

What were the results of the study?

This is a summary of the main results from this study. These are the results from all the participants combined. The individual results of each participant might be different and are not in this summary.

Other studies may provide new information or different results. Always talk to a doctor before making any treatment decisions.

Did the amount of CZP in the participants' blood change during pregnancy compared to after pregnancy?

Yes. Overall, the researchers found that the amount of CZP in the participants' blood **decreased** during pregnancy compared to after pregnancy.

To answer this question, the study doctors took blood samples from the participants before and after they received their CZP doses during the study. Then, the researchers measured the amount of CZP in the participants' blood samples and compared the results during their pregnancy to the results after their pregnancy.

The researchers also found that:

- The amount of CZP in the participants' blood in this study was within the same range as the amount of CZP found in the blood of participants who were not pregnant in other studies.
- The decrease in the amount of CZP was consistent during all 3 parts (trimesters) of the participants' pregnancies.

What medical problems did the study doctors report as possibly related to the study treatment?

This section is a summary of the medical problems that the participants had during the study that the doctors reported as **possibly related** to the study treatment. These medical problems are called **adverse reactions**. An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems, or requires hospital care. Other medical problems happened during this study, but the study doctors did not think they were possibly related to the study treatment, so they are not included in this summary.

Other studies may or may not show that these medical problems were related to the study treatment. The results from several studies are often needed to decide if a treatment causes an adverse reaction. Always talk to a doctor before making any treatment decisions.

Did any adverse reactions happen during this study?

Adverse reactions in this study

	Group 1 200 mg of CZP every 2 weeks (out of 15 participants)	Group 2 400 mg of CZP every 2 weeks (out of 1 participant)	Group 3 400 mg of CZP every 4 weeks (out of 5 participants)
How many participants had serious adverse reactions?	none	none	none
How many participants had adverse reactions?	6.7% (1)	none	none
How many participants left the study due to adverse reactions?	none	none	none

What adverse reactions did the participants have?

There was 1 participant who was receiving 200 mg of CZP every 2 weeks who had an adverse reaction of a common type of skin cancer called basal cell carcinoma. This was 6.7% of the participants in this group. This participant had a medical history and family history of basal cell carcinoma, and they did not stop taking the study treatment because of this adverse reaction.

What did the researchers learn from this study?

The results of this study have helped researchers learn more about using CZP in pregnant women living with chronic inflammatory conditions.

Deciding which treatments work best for patients almost always takes results from several studies. This summary shows only the main results from this one study. Other studies may provide new information or different results.

The purpose of this summary is only to share information. If you need medical advice about your own health or situation, please contact your doctor.

When this document was approved, further clinical studies with CZP in pregnant women were not planned.

Where can I learn more about this study?

You can find more information about this study at the websites listed below:

- www.clinicaltrials.gov/ct2/show/study/NCT04163016
- www.clinicaltrialsregister.eu/ctr-search/search?query=2019-003410-13

If you have questions about this study, UCB contact information is available at www.ucb.com/UCBcares.

Study Information

Protocol Number: UP0085

Study Sponsor: UCB Biopharma SRL sponsored this study. It is referred to as UCB in this summary.

Full Study Title: A Postmarketing, Multicenter, Longitudinal, Prospective, Pharmacokinetic, Phase 1b Study In Pregnant Women With Chronic Inflammatory Diseases Treated With Cimzia® (Certolizumab Pegol)

National Clinical Trial Number: NCT04163016

EudraCT Number: 2019-003410-13

Thank you

Participants in clinical studies belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

CISCRP REVIEW PANEL

This summary was last updated on 01 May 2024.
The final clinical study report is dated 24 October 2023.