

Clinical Study Results

Study Sponsor: UCB Biopharma SRL

Treatment Studied: Certolizumab pegol

Protocol Number: PS0005

Short Study Title: A study to learn how certolizumab pegol worked in people with psoriasis

Thank you!

UCB thanks all the participants of this study, which is also known as the CIMPASI-1 study. All the participants helped the researchers learn more about using certolizumab pegol in people with moderate or severe chronic plaque psoriasis. Certolizumab pegol is also called CDP870.

This is a summary of the main results of this study. An independent, non-profit organization called CISCRP helped prepare this summary of the study results.

We think it is important to share the results with the participants and the public. We hope this summary helps the participants understand and feel proud of 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 a doctor or study staff.

Why was the research needed?

Before a treatment is available to all patients, researchers do clinical studies to get information about how well the treatment works and about how safe it is.

The researchers in this study wanted to learn if certolizumab pegol worked in a large number of participants with chronic plaque psoriasis. They also wanted to learn if the participants had any medical problems during the study.

Chronic plaque psoriasis causes dry, red, scaly patches of skin. These patches are called plaques. They can form on any part of the body, but most often on the elbows, knees, scalp, and lower back. These plaques can also be itchy and painful, and can sometimes crack and bleed, especially around the joints.

Researchers think that these symptoms happen because some parts of the immune system are too active. Certolizumab pegol works by lowering the activity of an immune system protein called “tumor necrosis factor”.

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In this study, the researchers wanted to find out if certolizumab pegol lowered the number, size, or severity of skin plaques in people with chronic plaque psoriasis.

What were the main questions studied?

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

- Did certolizumab pegol reduce psoriasis symptoms?
- What medical problems did the study doctors think might be related to the study treatments?

Who participated in the study?

There were 234 men and women who participated in this study and took study treatment. They were 21 to 76 years old.

The study included participants who took study treatment in 5 countries: Canada, the Czech Republic, Germany, Hungary, and the United States.

In this study, the researchers planned to include participants who had already had chronic plaque psoriasis for at least 6 months.

Participants were in the study for up to about 3 years, but the whole study lasted for a little less than 4 years. The study started in December 2014 and ended in October 2018.

What treatments did the participants take?

The participants in this study took certolizumab pegol or a placebo through an injection under the skin. The placebo injection looked like the certolizumab pegol injection but did not have any treatment in it. The researchers used the placebo to help make sure the effects they found in the study were actually caused by certolizumab pegol.

The doses of certolizumab pegol were measured in milligrams, also called mg. The doses of certolizumab pegol used in this study were 200 mg and 400 mg. The participants were given certolizumab pegol or the placebo once every 2 weeks.

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There were 3 parts to this study.

Part 1 lasted for 16 weeks. During Part 1 the participants got either:



3 doses of 400 mg of certolizumab pegol and then 200 mg for the rest of this part



400 mg of certolizumab pegol



the placebo

During Part 1, the participants, study doctors, and most of the study staff did not know what treatment each participant was taking. UCB staff also did not know. Some studies are done this way because knowing what treatment the participants are taking can affect the results of the study. The study staff who gave injections to the participants knew what treatment the participants were getting. These members of the study staff were not involved in any other part of the study and did not tell other study staff what the participants were given.

At the start of the study, the researchers used a computer program to randomly choose if the participants took certolizumab pegol or the placebo. This helped make sure the treatments were chosen in an unbiased way. It also means that comparing the results for the treatments was as accurate as possible.

Part 2 lasted for 32 weeks. If the study treatment helped the participant's psoriasis in Part 1, the participant kept taking the same treatment in Part 2. For these participants, they, the study doctors, and most of the study staff did not learn what treatment the participant was given.

If the study treatment did not help the participant's psoriasis symptoms in Part 1, the participant could take 400 mg of certolizumab pegol in Part 2. For these participants, they, the study doctors, study staff, and UCB staff knew what the participant was given.

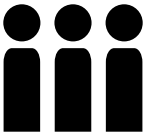

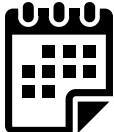
If the study treatment was not helping a participant's symptoms during Part 2, they left the study.

After Part 2 finished, UCB learned what treatment and dose each participant took in Part 1 and Part 2 so they could create a report of the results.

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Part 3 lasted for 96 weeks. In this part, all of the participants got 200 mg or 400 mg of certolizumab pegol. None of the participants got the placebo in this part. The participants, study doctors, study staff, and UCB staff knew how much certolizumab pegol the participants got. In Part 3, the dose of certolizumab pegol that the participants got could change depending on their symptoms.

The chart below shows an overview of the treatments the participants got during all parts of the study:

	Part 1	Part 2	Part 3
	<ul style="list-style-type: none"> 95 participants got 3 doses of 400 mg certolizumab pegol and then 200 mg certolizumab pegol for the rest of this part of the study 88 participants got 400 mg certolizumab pegol 51 participants got the placebo 	<ul style="list-style-type: none"> 79 participants got 200 mg certolizumab pegol 141 participants got 400 mg certolizumab pegol 3 participants got placebo 	<ul style="list-style-type: none"> 200 participants got 200 mg or 400 mg certolizumab pegol
	<ul style="list-style-type: none"> The participants were given all of the study treatments as injections 		
	<ul style="list-style-type: none"> The participants were given certolizumab pegol or placebo injections every 2 weeks for 16 weeks 	<ul style="list-style-type: none"> The participants were given certolizumab pegol or placebo injections every 2 weeks for 32 weeks 	<ul style="list-style-type: none"> The participants were given certolizumab pegol injections every 2 weeks for 96 weeks

What happened during this study?

This section shows how the study was 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 part lasted up to 5 weeks.

During Part 1 of the study, the participants visited their clinic 9 times. During this part, the participants were given certolizumab pegol or the placebo. Part 1 lasted 16 weeks.

During Part 2 of the study, the participants visited their clinic 16 times. During this part, the participants were given certolizumab pegol or the placebo. Part 2 lasted 32 weeks.

During Part 3 of the study, the participants visited the study clinic 47 times. During this part, the participants were given certolizumab pegol. Part 3 lasted 96 weeks.

After getting the last treatment, the participants visited their clinic 2 more times. The study doctors asked about their health and any medical problems they were having. This part of the study lasted up to 8 weeks.

During all parts of the study, the participants:



Were given certolizumab pegol or placebo through an injection once every 2 weeks



Had physical exams



Gave blood and urine samples



Answered questionnaires about their overall health and their symptoms

The study doctors:



Kept track of any medical problems reported by the participants or observed by the study doctors or study staff



Checked the participants' psoriasis symptoms

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.

Deciding which treatments work best usually takes results from several studies. Other studies may provide new information or different results. Always talk to a doctor before making any treatment decisions.

The results for Part 2 and Part 3 are not included in this section. This is because they were not a part of the main questions that the researchers wanted to answer.

Did certolizumab pegol reduce psoriasis symptoms?

Yes. In this study, the researchers found that psoriasis symptoms were reduced more in the participants who took certolizumab pegol than in those who took the placebo.

To answer this question, the study doctors checked how severe and how big the participants' psoriasis plaques were. From this, they could calculate a "Psoriasis Area and Severity Index" score, also called a PASI score. A low PASI score means less severe psoriasis.

The researchers then compared the participants' PASI scores at the end of Part 1 to their scores at the start of the study. Then, they determined how many participants' PASI scores had reduced by 75% or more during this part of the study. These participants are called "PASI75 responders".

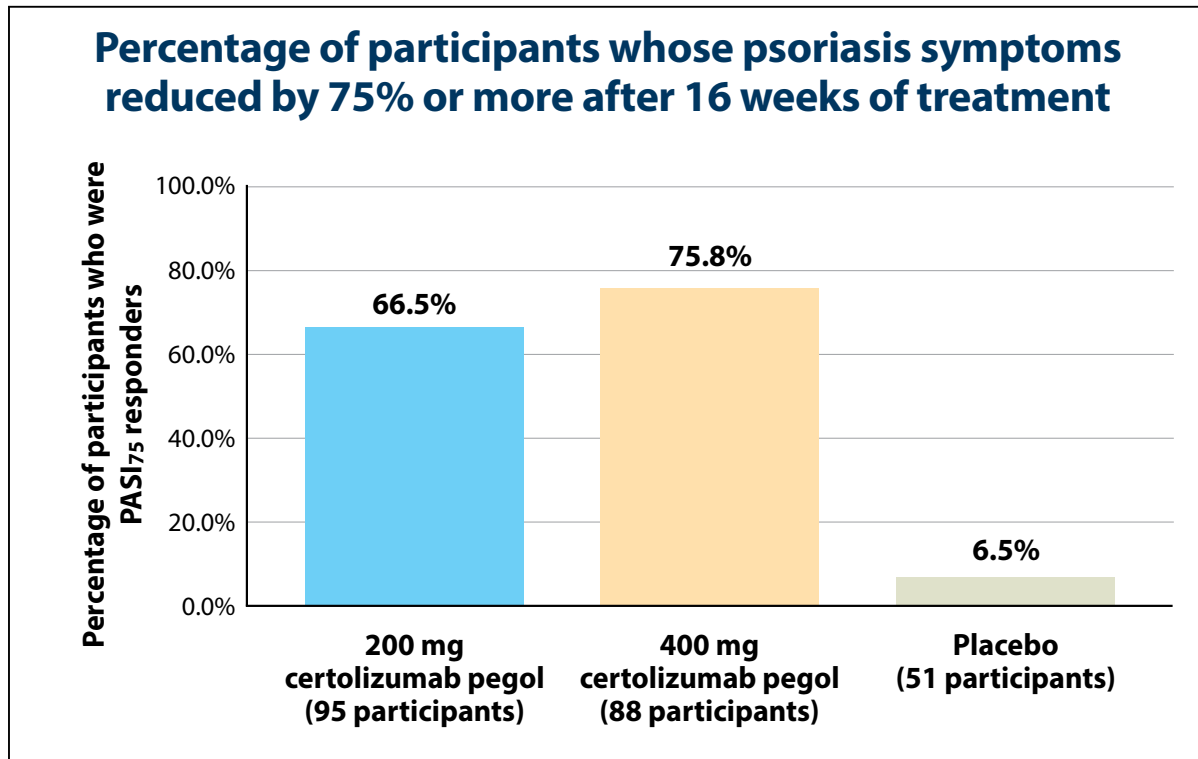
The researchers found that after 16 weeks of treatment:

- 66.5% of participants who were given 200 mg of certolizumab pegol were PASI75 responders.
- 75.8% of participants who were given 400 mg of certolizumab pegol were PASI75 responders.
- 6.5% of participants who were given the placebo were PASI75 responders.

This means that the participants who were given certolizumab pegol were more likely to have reduced psoriasis symptoms than the participants who were given the placebo.

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The graph below shows these results.



The study doctors also checked the participants' psoriasis symptoms using a measure called the "Physician's Global Assessment", also known as the PGA. The study doctors used the PGA to score the participants' psoriasis symptoms based on their overall severity. The PGA scores are:

- 4 – severe
- 3 – moderate
- 2 – mild
- 1 – almost clear
- 0 – clear

The researchers compared the participants' PGA scores at the end of Part 1 to their scores at the start of the study. Then, they determined how many participants' PGA scores had improved by 2 points or more and were clear or almost clear. These participants are called "PGA responders".

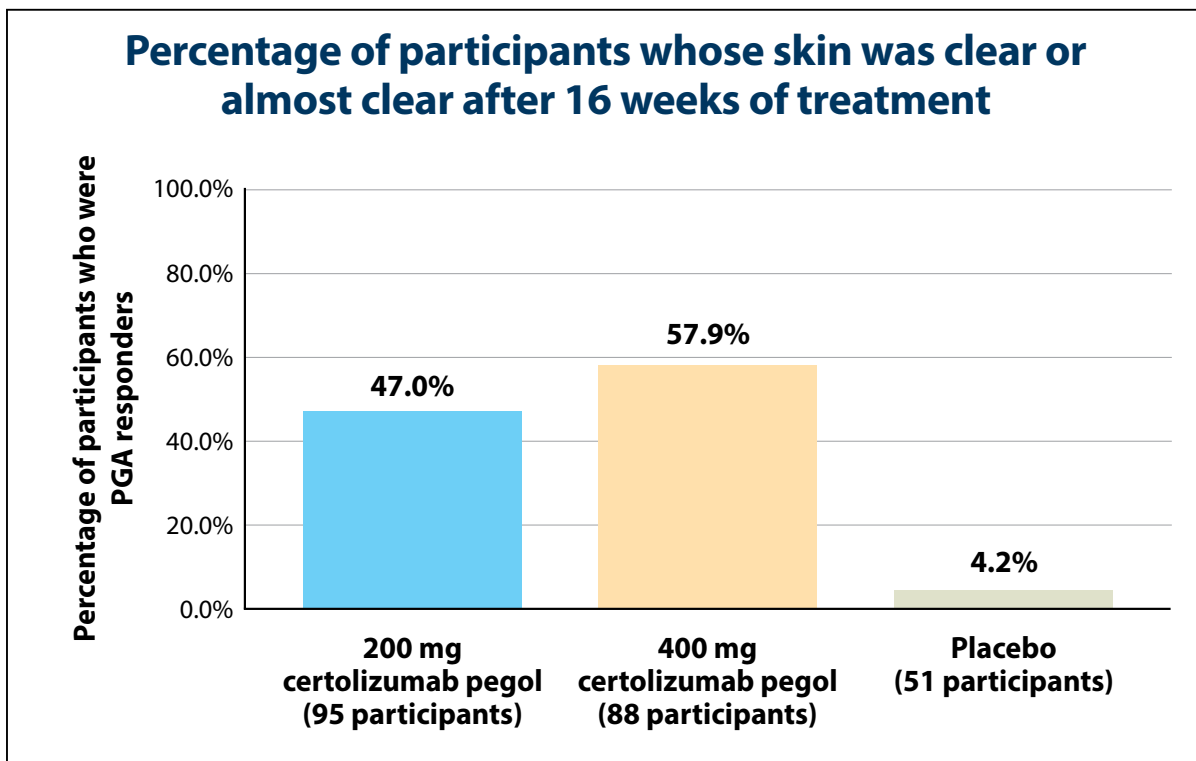
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The researchers found that after 16 weeks of treatment:

- 47.0% of participants who were given 200 mg of certolizumab pegol were PGA responders.
- 57.9% of participants who were given 400 mg of certolizumab pegol were PGA responders.
- 4.2% of participants who were given the placebo were PGA responders.

This meant that the participants who were given certolizumab pegol were more likely to have clear or almost clear skin after 16 weeks of treatment compared to the participants who were given a placebo.

The graph below shows these results.



What medical problems did the study doctors think might be related to the study treatments?

This section is a summary of the medical problems the participants had during the study that the study doctors thought might be related to the study treatments. In this summary, these medical problems are called “adverse reactions”.

This summary also includes information about serious adverse reactions. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

Other studies may or may not show that these medical problems were related to the study treatments. The results from several studies are often needed to decide what medical problems are actually caused by a treatment. Always talk to a doctor before making any treatment decisions.

How many participants had serious adverse reactions?

The table below shows what percentage of participants had serious adverse reactions and deaths in this study. The numbers in parentheses are the number of participants who had a serious adverse reaction. The serious adverse reactions that happened in Part 1 and Part 2 were also included in the information for the whole study.

Percentage of participants who had serious adverse reactions

	During Part 1	During Part 1 and Part 2		During the whole study	
	Placebo (out of 51 participants)	200 mg certolizumab pegol (out of 100 participants)	400 mg certolizumab pegol (out of 144 participants)	200 mg certolizumab pegol (out of 188 participants)	400 mg certolizumab pegol (out of 167 participants)
How many participants had serious adverse reactions?	0.0% (0)	0.0% (0)	2.8% (4)	0.0% (0)	2.4% (4)
How many participants died due to serious adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

What serious adverse reactions did the participants have?

The table below shows the serious adverse reactions that happened in the study. The numbers in percentages show the percentage of participants who had the serious adverse reaction. The numbers in parentheses are the number of participants who had a serious adverse reaction. The serious adverse reactions that happened in Part 1 and Part 2 were also included in the information for the whole study.

Serious adverse reactions during the study					
	During Part 1	During Part 1 and Part 2		During the whole study	
	Placebo (out of 51 participants)	200 mg certolizumab pegol (out of 100 participants)	400 mg certolizumab pegol (out of 144 participants)	200 mg certolizumab pegol (out of 188 participants)	400 mg certolizumab pegol (out of 167 participants)
<u>Infected lymph nodes</u>	0.0% (0)	0.0% (0)	0.7% (1)	0.0% (0)	0.6% (1)
<u>Redness at the site of an injection</u>	0.0% (0)	0.0% (0)	0.7% (1)	0.0% (0)	0.6% (1)
<u>Severe and potentially life-threatening allergic reaction</u>	0.0% (0)	0.0% (0)	0.7% (1)	0.0% (0)	0.6% (1)
<u>Skin infection</u>	0.0% (0)	0.0% (0)	0.7% (1)	0.0% (0)	0.6% (1)

How many participants had any adverse reactions?

During Part 1 and Part 2 of the study, adverse reactions happened in:

- 14.0% of participants who were given 200 mg of certolizumab pegol during these parts of the study. This was 14 out of 100 participants.
- 19.4% of participants who were given 400 mg of certolizumab pegol during these parts of the study. This was 28 out of 144 participants.
- 7.8% of participants who were given the placebo during Part 1 of the study. This was 4 out of 51 participants.

During the whole study, adverse reactions happened in:

- 15.4% of participants who were given 200 mg of certolizumab pegol during any part of the study. This was 29 out of 188 participants.
- 21.0% of participants who were given 400 mg of certolizumab pegol during any part of the study. This was 35 out of 167 participants.

What adverse reactions did the participants have?

The most common adverse reaction was inflammation of the nose and throat area. The table below shows the adverse reactions that happened in 5% or more participants in any group. There were other adverse reactions, but these happened in fewer participants. The numbers in percentages show the percentage of participants who had the serious adverse reaction. The numbers in parentheses are the number of participants who had a serious adverse reaction. The adverse reactions that happened in Part 1 and Part 2 of the study were also in the information for the whole study.

Adverse reactions in 5.0% or more of participants in any treatment group during the study					
	During Part 1	During Part 1 and Part 2		During the whole study	
	Placebo (out of 51 participants)	200 mg certolizumab pegol (out of 100 participants)	400 mg certolizumab pegol (out of 144 participants)	200 mg certolizumab pegol (out of 188 participants)	400 mg certolizumab pegol (out of 167 participants)
<u>Inflammation of the nose and throat area</u>	3.9% (2)	5.0% (5)	5.6% (8)	5.3% (10)	7.2% (12)
Infection of the nose, sinuses, and throat	2.0% (1)	6.0% (6)	1.4% (2)	3.7% (7)	2.4% (4)

How has this study helped patients and researchers?

The results of this study have helped researchers learn more about using certolizumab pegol in people with chronic plaque psoriasis.

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.

The results of this trial may be used in other studies to compare certolizumab pegol with other treatments for people who have chronic plaque psoriasis.

At the time this study ended, further clinical studies in chronic plaque psoriasis with certolizumab pegol were ongoing.

Where can I learn more about this study?

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

- <http://www.clinicaltrials.gov/ct2/show/NCT02326298>
- <https://www.clinicaltrialsregister.eu/ctr-search/search?query=2014-003513-28>

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

Study Information

Protocol Number: PS0005

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

Full Study Title: A Phase 3, Multicenter, Randomized, Double-Blind, Parallel-Group, Study Followed by a Dose-Blind Period and Open-Label Follow-Up to Evaluate the Efficacy and Safety of Certolizumab Pegol in Subjects With Moderate to Severe Chronic Plaque Psoriasis

National Clinical Study Number: NCT02326298

EudraCT Number: 2014-003513-28

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.

Glossary

Description	Also called
Infected lymph nodes	Lymph nodes are part of the immune system and contain cells that fight infections. Also called “lymphadenitis”.
Redness at the site of an injection	“injection site reaction”
Severe and potentially life-threatening allergic reaction	“anaphylactoid reaction”
Skin infection	A skin infection caused by bacteria. Also called “erysipelas”.
Inflammation of the nose and throat area	“nasopharyngitis”
Infection of the nose, sinuses, and throat	“upper respiratory tract infection”



This summary was last updated on 28 June 2021.
The final clinical study report is dated 16 May 2019.