# Clinical Study Results

Inspired by patients. Driven by science.

**Study Sponsor:** UCB Biopharma SRL

**Treatment Studied:** Certolizumab pegol

**Protocol Number:** PS0003

**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 CIMPACT 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”.

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. They also wanted to learn more about the safety of certolizumab pegol and another psoriasis treatment called etanercept. Etanercept works in a similar way to certolizumab pegol.

## 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 559 men and women who participated in this study and got study treatment. They were 18 to 80 years old.

The study included participants who took study treatment in 9 countries: Bulgaria, the Czech Republic, France, Germany, Hungary, the Netherlands, Poland, the United Kingdom, 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.

Each participant was in the study for up to just over 3 years, but the whole study lasted for a little less than 4 years. The study started in February 2015 and ended in December 2018.

# What treatments did the participants take?

The participants in this study got certolizumab pegol, etanercept, 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 participants who were given the placebo got it once every 2 weeks.

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 who were given certolizumab pegol got it once every 2 weeks.

The dose of etanercept used in this study was 50 mg. The participants who got etanercept got it twice a week.

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 for 6 weeks and then 200 mg for 10 weeks


400 mg of certolizumab pegol for 16 weeks


50 mg of etanercept for 12 weeks


the placebo for 16 weeks

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 getting can affect the results of the study. The study staff who gave injections to the participants who were getting etanercept knew what treatment they were giving. This was because etanercept was given twice a week, while the placebo and certolizumab pegol were only given once every 2 weeks. These members of the study staff only gave the participants the injections. They were not involved in any other part of the study and did not tell other study staff which participants were getting etanercept.

At the start of Part 1, the researchers used a computer program to randomly choose if the participants were given certolizumab pegol, etanercept, 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 their symptoms improved in Part 1, the participants who got etanercept or either dose of certolizumab pegol in Part 1 got one of the following treatments in Part 2:

 200 mg of certolizumab pegol

 400 mg of certolizumab pegol

 the placebo

The researchers used the same computer program to randomly choose the Part 2 treatments for these participants. These participants, the study doctors, and most of the study staff did not know what treatment each participant was getting. UCB staff also did not know.

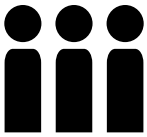
For the participants who got the placebo in Part 1, if their symptoms improved, then they continued to get the placebo in Part 2. These participants, the study doctors, and most of the study staff did not know what treatment these participants were getting. UCB staff also did not know.

All of the participants whose symptoms did not improve in Part 1 got 400 mg of certolizumab pegol in Part 2. These participants, the study doctors, study staff, and UCB staff knew that these participants were getting 400 mg of certolizumab pegol. If these participants' symptoms still did not improve during Part 2, then they left the study at the end of Part 2.

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.

**Part 3 lasted for 96 weeks.** In Part 3, all of the participants took 200 mg or 400 mg of certolizumab pegol. The participants, study doctors, study staff, and UCB staff knew how much certolizumab pegol the participants took. In Part 3, the dose of certolizumab pegol that the participants took could change depending on their symptoms.

The chart below shows an overview of the study:

| | Part 1 | Part 2 | Part 3 |
|---|---|---|---|
|  | • 165 participants got 3 doses of 400 mg certolizumab pegol and then 200 mg certolizumab pegol for the rest of this part of the study<br>• 167 participants got 400 mg certolizumab pegol<br>• 170 participants got 50 mg etanercept<br>• 57 participants got the placebo | • 188 participants got 200 mg certolizumab pegol<br>• 273 participants got 400 mg certolizumab pegol<br>• 73 participants got placebo | • 245 participants got 200 mg certolizumab pegol<br>• 227 participants got 400 mg certolizumab pegol |
|  | • The participants were given all of the study treatments as injections | | |
|  | The participants were given:<br>• certolizumab pegol or the placebo every 2 weeks for 16 weeks, or<br>• etanercept injections twice a week for 12 weeks | • The participants were given certolizumab pegol or placebo injections every 2 weeks for 32 weeks | • 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 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 part lasted up to 5 weeks.

**During Part 1 of the study,** the participants visited their clinic up to 27 times. During this part, the participants were given certolizumab pegol, etanercept, 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 their clinic up to 8 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 10 weeks.

# 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.

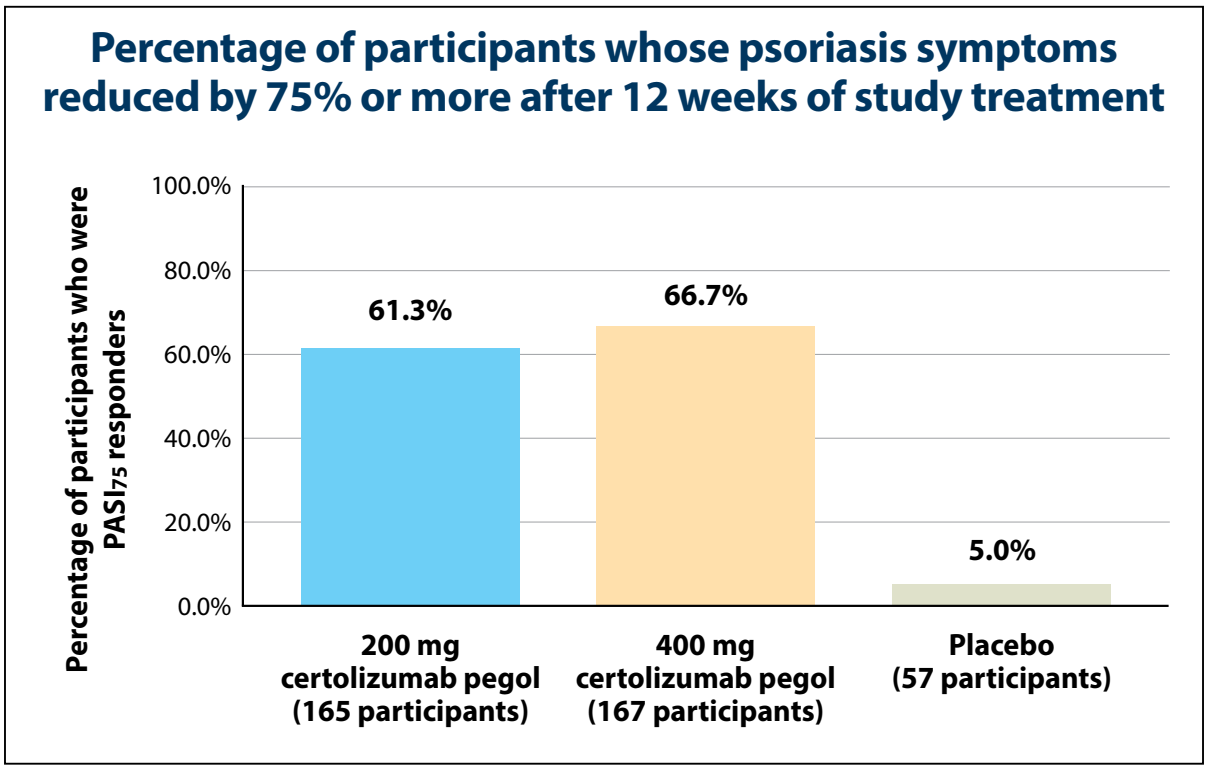
The researchers then compared the participants' PASI scores after 12 weeks of treatment to their scores at the start of the study. Then, they determined how many participants' PASI scores had reduced by 75% or more during this part of the study. These participants are called "PASI75 responders".

The researchers found that after 12 weeks of treatment:

- 61.3% of participants who were given 200 mg of certolizumab pegol were PASI75 responders.
- 66.7% of participants who were given 400 mg of certolizumab pegol were PASI75 responders.
- 5.0% 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.

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.

There were 2 participants in the etanercept group in Part 1 who did not get any study treatment. The results below include the 557 participants who received at least 1 dose of treatment.

## How many participants had serious adverse reactions?

The serious adverse reactions that happened in Part 1 and Part 2 were also included in the information for the whole study.

In Part 1, none of the participants had serious adverse reactions.

In Part 2, serious adverse reactions happened in:

- 0.5% of the participants who got 200 mg of certolizumab pegol. This was 1 out of 188 participants.
- 1.1% of the participants who got 400 mg of certolizumab pegol. This was 3 out of 273 participants
- 1.4% of the participants who got the placebo. This was 1 out of 73 participants.

In the whole study, serious adverse reactions happened in:

- 1.6% of the participants who got 200 mg of certolizumab pegol. This was 6 out of 373 participants.
- 1.2% of the participants who got 400 mg of certolizumab pegol. This was 5 out of 412 participants.

## What serious adverse reactions did the participants have?

No participants had serious adverse reactions in Part 1. The table below shows the serious adverse reactions that happened in Parts 2 and 3 of 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. Some of the participants had more than 1 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 Part 2**

| | 200 mg certolizumab pegol (out of 188 participants) | 400 mg certolizumab pegol (out of 273 participants) | Placebo (out of 73 participants) |
|---|---|---|---|
| Inflammation of the liver | 0.5% (1) | 0.0% (0) | 0.0% (0) |
| A life-threatening reaction to an infection | 0.0% (0) | 0.4% (1) | 0.0% (0) |
| A life-threatening reaction to an infection caused by E. coli bacteria | 0.0% (0) | 0.4% (1) | 0.0% (0) |
| Tuberculosis | 0.0% (0) | 0.4% (1) | 0.0% (0) |
| Inflammation of the kidneys, usually due to bacteria | 0.0% (0) | 0.4% (1) | 0.0% (0) |
| Inflammation of the large intestine, also called the colon | 0.0% (0) | 0.0% (0) | 1.4% (1) |

| Serious adverse reactions during the whole study | | |
|---|---|---|
| | 200 mg certolizumab pegol (out of 373 participants) | 400 mg certolizumab pegol (out of 412 participants) |
| Inflammation of the inside of the eyeball | 0.3% (1) | 0.0% (0) |
| Thin layer at the back of the eye comes loose | 0.3% (1) | 0.0% (0) |
| Infection of the bones caused by bacteria | 0.3% (1) | 0.0% (0) |
| Inflammation of the joints between the lower spine and pelvis | 0.3% (1) | 0.0% (0) |
| Pus-filled lump under the surface of the skin | 0.3% (1) | 0.0% (0) |
| Infection in the deeper layer of the skin | 0.3% (1) | 0.0% (0) |
| Sudden heart attack | 0.3% (1) | 0.0% (0) |
| Infection of the main airways of the lungs | 0.3% (1) | 0.0% (0) |
| Inflammation of the liver | 0.3% (1) | 0.0% (0) |
| A life-threatening reaction to an infection | 0.0% (0) | 0.2% (1) |
| A life-threatening reaction to an infection caused by E. coli bacteria | 0.0% (0) | 0.2% (1) |
| Tuberculosis | 0.0% (0) | 0.2% (1) |
| Inflammation of the kidneys, usually due to bacteria | 0.0% (0) | 0.2% (1) |
| A type of kidney cancer called clear cell renal cell carcinoma | 0.0% (0) | 0.2% (1) |
| Kidneys suddenly stop working properly | 0.0% (0) | 0.2% (1) |
| Sudden loss of liver function | 0.0% (0) | 0.2% (1) |

## How many participants had any adverse reactions?

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

- 12.7% of participants who got 200 mg of certolizumab pegol. This was 21 out of 165 participants.
- 14.4% of participants who got 400 mg of certolizumab pegol. This was 24 out of 167 participants.
- 11.9% of the participants who were given 50 mg of etanercept. This was 20 out of 168 participants.
- 22.8% of participants who were given the placebo. This was 13 out of 57 participants.

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

- 13.3% of participants who were given 200 mg of certolizumab pegol. This was 25 out of 188 participants.
- 13.6% of participants who were given 400 mg of certolizumab pegol. This was 37 out of 273 participants.
- 20.5% of participants who were given the placebo. This was 15 out of 73 participants.

During the whole study, adverse reactions happened in:

- 20.6% of participants who were given 200 mg of certolizumab pegol during any part of the study. This was 77 out of 373 participants.
- 18.7% of participants who were given 400 mg of certolizumab pegol during any part of the study. This was 77 out of 412 participants.

## What adverse reactions did the participants have?

The most common adverse reaction was infection of the nose, sinuses, and throat. The tables below show the adverse reactions that happened in 2% 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 included in the information for the whole study.

| Adverse reactions in 2% or more of participants in any treatment group | | | | |
|---|---|---|---|---|
| **During Part 1** | | | | |
| | 200 mg certolizumab pegol (out of 165 participants) | 400 mg certolizumab pegol (out of 167 participants) | 50 mg etanercept (out of 168 participants) | Placebo (out of 57 participants) |
| Infection of the nose, sinuses, and throat | 0.6% (1) | 3.0% (5) | 1.2% (2) | 1.8% (1) |
| Inflammation of the nose and throat area | 1.2% (2) | 1.2% (2) | 0.0% (0) | 5.3% (3) |
| Redness at the site of an injection | 0.0% (0) | 0.0% (0) | 3.0% (5) | 0.0% (0) |

| During Part 2 | | | |
|---|---|---|---|
| | 200 mg certolizumab pegol (out of 188 participants) | 400 mg certolizumab pegol (out of 273 participants) | Placebo (out of 73 participants) |
| Infection of the nose, sinuses, and throat | 1.6% (3) | 1.8% (5) | 4.1% (3) |
| Inflammation of the nose and throat area | 1.1% (2) | 1.1% (3) | 5.5% (4) |

| During the whole study | | |
|---|---|---|
| | 200 mg certolizumab pegol (out of 373 participants) | 400 mg certolizumab pegol (out of 412 participants) |
| Infection of the nose, sinuses, and throat | 2.4% (9) | 2.9% (12) |
| Inflammation of the nose and throat area | 2.4% (9) | 1.7% (7) |
| Redness at the site of an injection | 0.0% (0) | 0.2% (1) |

# 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:

- www.clinicaltrials.gov/ct2/show/NCT02346240
- www.clinicaltrialsregister.eu/ctr-search/search?query= 2014-003492-36

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

# Study Information

**Protocol Number:** PS0003

**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, Placebo- and Active-Controlled Study Followed by a Placebo-Controlled Maintenance 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:** NCT02346240

**EudraCT Number:** 2014-003492-36

## *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 |
|---|---|
| Inflammation of the inside of the eyeball | This is usually caused by an infection. Also called “endophthalmitis”. |
| Thin layer at the back of the eye comes loose | “retinal detachment” |
| Infection of the bones caused by bacteria | “osteomyelitis” |
| Inflammation of the joints between the lower spine and pelvis | “sacroilitis” |
| Pus-filled lump under the surface of the skin | “subcutaneous abscess” |
| Infection in the deeper layer of the skin | “cellulitis” |
| Sudden heart attack | “acute myocardial infarction” |
| Infection of the main airways of the lungs | “bronchitis” |
| Inflammation of the liver | Usually caused by a virus. Also called “hepatitis”. |
| A life-threatening reaction to an infection | “sepsis” |
| A life-threatening reaction to an infection caused by E. coli bacteria | “escherichia sepsis” |
| Inflammation of the kidneys, usually due to bacteria | “pyelonephritis” |
| A type of kidney cancer called clear cell renal cell carcinoma | “clear cell RCC” |
| Kidneys suddenly stop working properly | “acute kidney injury” |
| Sudden loss of liver function | “acute hepatic failure” |
| Inflammation of the large intestine, also called the colon | This is caused by an overgrowth of bacteria. Also called “pseudomembranous colitis”. |
| Infection of the nose, sinuses, and throat | “upper respiratory tract infection” |
| Inflammation of the nose and throat area | “nasopharyngitis” |
| Redness at the site of an injection | “injection site erythema” |


This summary was last updated on 30 June 2021.
The final clinical study report is dated 18 June 2019.