

Clinical Study Results



Study Sponsor: UCB Biopharma SPRL

Treatment Studied: Certolizumab pegol

Protocol Number: RA0044

Short Study Title: A study to learn if certolizumab pegol works in Chinese participants with active rheumatoid arthritis

Thank you!

UCB thanks all the participants of this study. All the participants helped the researchers learn more about using certolizumab pegol in people with rheumatoid arthritis, also called RA.

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 your study doctor or the 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 plus methotrexate worked in a large number of participants with active RA. They also wanted to learn if the participants had any medical problems during the study.

RA is an immune system disease that causes pain, swelling, and damage to joints. Doctors often recommend that patients first take methotrexate to treat their RA. But, sometimes people with RA need other treatments to control their RA.

Certolizumab pegol blocks a protein that is 1 of the causes of RA. When this study started, certolizumab pegol was not available in China as a treatment for RA. In this study, the researchers wanted to learn if certolizumab pegol improved Chinese participants' RA when they were already taking methotrexate.

What were the main questions studied?

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

- How many participants had their RA improve?
- What medical problems did the participants have during the study?

Who participated in the study?

There were 429 men and women in the People's Republic of China who participated in this study and took study treatments. They were 20 to 77 years old.

In this study, the researchers planned to include participants who:

- Had RA for at least 6 months
- Had RA that the researchers considered active based on their number of tender and swollen joints and blood tests results showing inflammation
- Had taken methotrexate for at least 3 months in a row before the study, but still had active RA

Each participant was in the study for up to about 38 weeks, but the whole study lasted about 2 years. The study started in July 2014 and ended in June 2016.

What treatments did the participants take?

The participants in this study took either:

- certolizumab pegol plus methotrexate
- a placebo plus methotrexate

The placebo looked like certolizumab pegol but did not have any certolizumab pegol in it. The researchers used the placebo to help make sure the effects of certolizumab pegol they found in the study were actually caused by it.

Doses of certolizumab pegol and methotrexate were measured in milligrams, also called mg. Each participant's dose of methotrexate was based on the dose they took before the study. Certolizumab pegol was given through a needle under the skin, also called an injection. Methotrexate was taken as a pill by mouth.

None of the participants, study doctors, or study staff knew 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. After the study was completed, UCB learned what treatment each participant took so they could create a report of the results.














The researchers used a computer program to randomly choose if the participants took certolizumab pegol plus methotrexate or the placebo plus methotrexate. This helped make sure the treatments were chosen fairly and comparing the results of the treatments was as accurate as possible.

During this study:

- 316 participants took certolizumab pegol plus methotrexate
- 113 participants took the placebo plus methotrexate

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The chart below shows the treatments the researchers planned to study:





Certolizumab pegol plus methotrexate	Placebo plus methotrexate
 Certolizumab pegol injection  Methotrexate as a pill	 The placebo injection  Methotrexate as a pill
 Certolizumab pegol every 2 weeks for up to 22 weeks  Methotrexate every week for up to 22 weeks	 The placebo every 2 weeks for up to 22 weeks  Methotrexate every week for up to 22 weeks
 First 3 doses of certolizumab pegol: <ul style="list-style-type: none"> • 400 mg given as 2 injections of 200 mg each  All other doses of certolizumab pegol: <ul style="list-style-type: none"> • 200 mg given as 1 injection of 200 mg  Doses of methotrexate at least 10 mg each week	 The placebo had no medicine in it  Doses of methotrexate at least 10 mg each week

What happened during the study?

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

Before the study started, the participants visited the clinic at least 1 time. All the participants decided to take part after learning about the study. 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 be in the study. This part could take up to 42 days.

During the study:

	The study doctors counted the participants' number of swollen and tender joints, and rated how their RA was doing.
	The study doctors kept track of any medical problems reported by the participants or observed by the study doctors or study staff.
	The participants rated how their RA was making them feel.
	The participants gave blood and urine samples at some clinic visits.

The main part of the study lasted for 24 weeks. During the main part, the participants visited the clinic every 2 weeks.

At 12 weeks into the main part of the study, the researchers checked to see if the participants' RA improved. To do this, the researchers used the “ACR20 criteria,” also called the ACR20. The ACR20 is a way to look at RA improvement and is based on:

- The number of swollen and tender joints
- The study doctor's rating of the participants' RA
- The participants' rating of how their RA makes them feel
- The results of a blood test called CRP that measures inflammation

The participants with at least 20% improvement in their RA met the ACR20 criteria and were called “ACR20 responders.” ACR20 responders could stay in the study. They got their final injection of study treatment 2 weeks before the main part ended.

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The participants who were not ACR20 responders stopped taking study treatments or joined another certolizumab pegol study.

At the end of the main part of the study, the participants could choose to join another certolizumab study. The participants who did not join the other study had a final clinic visit 10 weeks after their final injection of study treatment.

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 researchers included 425 of the 429 participants in the results shown below. They did not include the participants who had changes from the study plan that might have affected the results in any way. The researchers did this to make sure that the participants were included fairly when they studied the results.

How many participants had their RA improve?

The researchers wanted to know how many participants were ACR20 responders after being in the study for 24 weeks. The participants who were ACR20 responders were considered “improved.”

The researchers studied the percentage of ACR20 responders among the participants who took certolizumab pegol plus methotrexate and among the participants who took the placebo plus methotrexate.

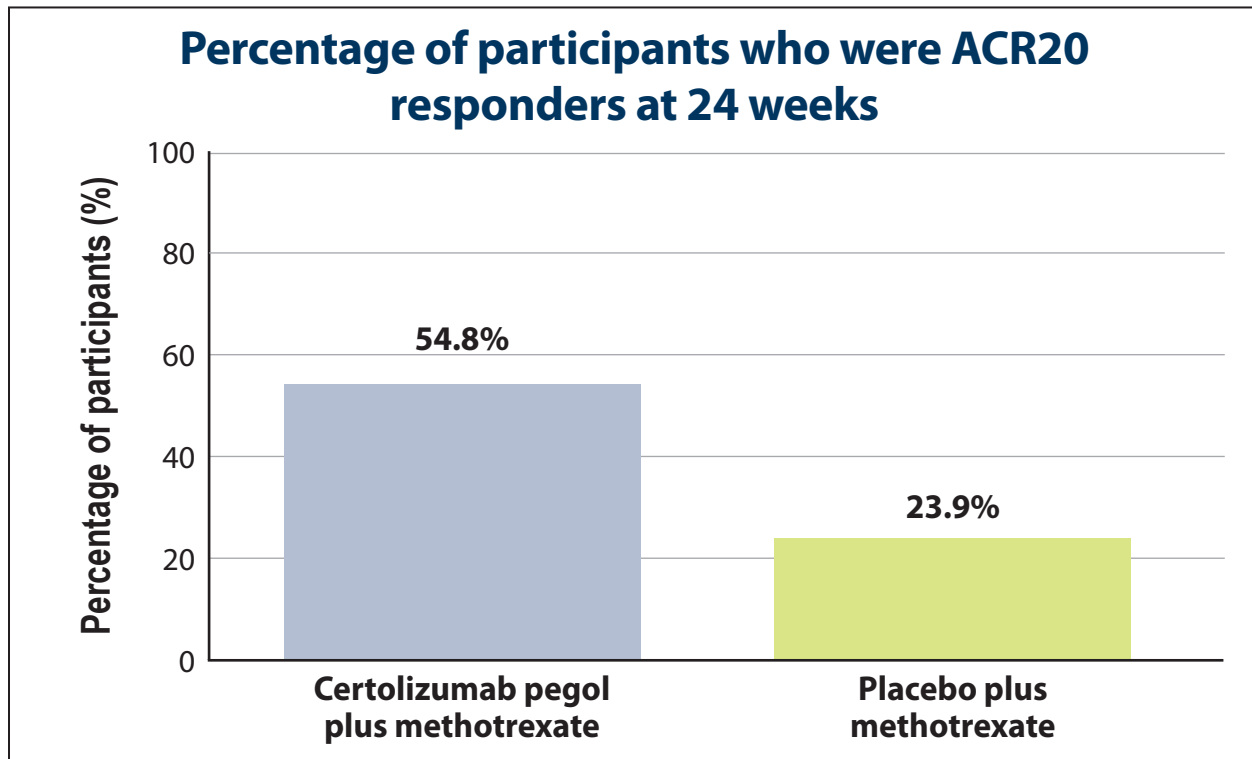
The researchers learned that a higher percentage of participants who took certolizumab pegol plus methotrexate were ACR20 responders.

The percentage of ACR20 responders was:

- 54.8% of the participants who took certolizumab pegol plus methotrexate. This was 171 out of 312 participants.
- 23.9% of the participants who took the placebo plus methotrexate. This was 27 out of 113 participants.

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The graph below shows these results:



What medical problems did the participants have?

This section is a summary of the medical problems the participants had during the study that the doctors thought might be related to the treatments. These medical problems are called “adverse reactions.” Some participants had more than 1 adverse reaction.

An adverse reaction is considered “serious” when it puts the participant’s life at risk, requires hospitalization, causes disability, causes a baby being born with medical problems, or may have turned into one of these problems if not treated.

These adverse reactions may or may not be caused by the treatments in the study. The results from several studies are needed to decide if a treatment causes an adverse reaction.

The information below includes all 429 participants. This is because all the participants got either certolizumab pegol or the placebo at least 1 time.

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How many participants had serious adverse reactions?

In this study, serious adverse reactions happened in:

- 3.2% of the participants who took certolizumab pegol plus methotrexate. This was 10 out of 316 participants.
- None of the participants who took the placebo plus methotrexate. This was 0 out of 113 participants.

There was 1 participant who died due to serious adverse reactions. The participant was taking certolizumab pegol plus methotrexate. These serious adverse reactions were:

- Lung infection
- Build-up of fluid in the space between the lung's lining and the chest cavity
- Lump in or on the lungs that is more than 3 centimeters across
- Abnormal build-up of fluid in the abdomen
- Sudden stop of the heart beating
- Failure to get enough oxygen from the lungs to the blood

What serious adverse reactions did the participants have?

The serious adverse reactions that happened in more than 1 participant are shown below. Each of these happened in 2 participants:

- Lump in or on the lungs that is more than 3 centimeters across
- Lung disease caused by the bacteria called Mycobacterium tuberculosis
- Lung infection

There were other serious adverse reactions, but these happened in fewer participants.

How many participants had any adverse reactions?

In this study, adverse reactions that were serious or not serious happened in:

- 45.9% of the participants who took certolizumab pegol plus methotrexate. This was 145 out of 316 participants.
- 42.5% of the participants who took the placebo plus methotrexate. This was 48 out of 113 participants.

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What adverse reactions did the participants have?

In this study, the most common adverse reactions were infection of the nose, sinuses, and throat and infection caused by the bacteria called Mycobacterium tuberculosis, without it causing sickness. They were the most common adverse reactions in both treatment groups.

The table below shows the adverse reactions that happened in 5% or more of the participants in either treatment group. This means they happened in at least 1 out of every 20 participants in either treatment group. There were other adverse reactions, but they happened in fewer participants.

Adverse reactions in 5% or more of participants in either treatment group

	Certolizumab pegol plus methotrexate (out of 316 participants)	Placebo plus methotrexate (out of 113 participants)
<u>Infection of the nose, sinuses, and throat</u>	8.2% (26)	7.1% (8)
<u>Infection caused by the bacteria called Mycobacterium tuberculosis, without it causing sickness</u>	7.6% (24)	6.2% (7)
<u>Increase of a protein called alanine aminotransferase</u>	4.4% (14)	5.3% (6)

How has this study helped patients and researchers?

The results of this study have helped researchers learn more about using certolizumab pegol in people who have RA. The results may be used in other studies to compare certolizumab pegol with other treatments for people who have a similar condition.

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 study ended, further clinical studies with certolizumab pegol were planned.

Where can I learn more about this study?

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

- <https://clinicaltrials.gov/ct2/show/NCT02151851?term=RA0044&rank=2>

If you have questions about this study, you can contact UCB by email at datasharing@ucb.com.

Study Information

Protocol Number: RA0044

Study Sponsor: UCB Biopharma SPRL sponsored this study. It was previously called UCB Pharma SA and is referred to as UCB in this summary.

Full Study Title: A phase 3, multicenter, double-blind, placebo-controlled, parallel group, randomized, 24-week study to evaluate the safety and efficacy of certolizumab pegol as additional medication to methotrexate in Chinese subjects with active rheumatoid arthritis who have an incomplete response to methotrexate

National Clinical Study Number: NCT02151851

Glossary

Abnormal build-up of fluid in the abdomen:	Also called “ascites.”
Build-up of fluid in the space between the lung’s lining and the chest cavity:	Also called “pleural effusion.”
Failure to get enough oxygen from the lungs to the blood:	Also called “respiratory failure.”
Increase of a protein called alanine aminotransferase:	Alanine aminotransferase is made by the liver and other parts of the body. An increase is also called “alanine aminotransferase increased.”
Infection caused by the bacteria called Mycobacterium tuberculosis, without it causing sickness:	Also called “latent tuberculosis.”
Infection of the nose, sinuses, and throat:	Also called “upper respiratory tract infection.”
Lump in or on the lungs that is more than 3 centimeters across:	This is also called “pulmonary mass.” The mass is sometimes found using an x-ray or other picture of the lungs. The lump also might be found other ways, including by surgery.
Lung disease caused by the bacteria called Mycobacterium tuberculosis:	Also called “pulmonary tuberculosis.”
Lung infection:	Also called “pneumonia.”
Sudden stop of the heart beating:	Also called “cardiac arrest.”

Thank you!

The 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.



This summary was last updated on 24 September 2019.
The amended final clinical study report is dated 16 March 2017.