Clinical Study Results

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Study Sponsor: Amgen Inc.

Treatment Studied: Romosozumab

Protocol Number: 20110174

Short Study Title: A study to learn how romosozumab worked in men with osteoporosis

Thank you

UCB and Amgen thank all the participants of this study. All the participants helped the researchers learn more about using romosozumab in men who have osteoporosis. Romosozumab is also called AMG 785. While Amgen conducted this study, UCB and Amgen have worked together to develop romosozumab.

This is a summary of the main results of this study. This study is sometimes called the BRIDGE 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 study doctor. If you participated in this study and have questions about the results, please speak with a study 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 romosozumab worked in male participants with osteoporosis. They also wanted to learn if the participants had any medical problems during the study.

In people with osteoporosis, bones break down and become weak. When this happens, it becomes more likely that their bones will fracture. The study drug, romosozumab, was developed to help slow down or stop osteoporosis. It works by helping new bone to form.

Doctors can check bone health by measuring the amount of bone minerals, like calcium, in bone tissue. This is also called bone density. To do this, they use an X-ray. In this study, the researchers wanted to find out if romosozumab increased the bone density in the lower spine in men with osteoporosis.

What were the main questions studied?

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

- Did romosozumab increase the participants' bone density in their lower spine?
- What medical problems did the participants have during the study?

Who participated in the study?

There were 245 men who participated in this study and took study treatment. They were 55 to 89 years old.

The study included participants in 9 countries: Belgium, Colombia, the Czech Republic, Denmark, Japan, Poland, Russia, Switzerland, and the United States.

In this study, the researchers planned to include men with osteoporosis who:

- Had lower than average bone density in the spine, hip, or upper leg
- Did not have very low bone density overall
- Were not receiving any treatment for their osteoporosis
- Did not have other serious health problems

Participants were in the study for about 1 year and 4 months and the whole study lasted for 1 year and 8 months. The study started in June 2014 and ended in January 2016.

What treatments did the participants take?

The participants in this study got romosozumab or a placebo through a needle under their skin, also known as an injection. The placebo injection looked like the romosozumab injection but did not have any treatment in it. The researchers used the placebo to help make sure the effects of romosozumab they found in the study were actually caused by it.

Each dose of romosozumab in the injection was 210 milligrams, also called mg, given through 3 injections. The participants got a dose of romosozumab or placebo once a month.

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

The researchers used a computer program to randomly choose if the participants were given romosozumab or the placebo. This helped make sure the treatments were chosen fairly and comparing the results for the treatments was as accurate as possible.

In this study, there were 163 participants who were planned to get romosozumab and 82 participants who were planned to get the placebo.

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

	• 163 participants were planned to get romosozumab • 82 participants were planned to get the placebo
	• The participants got each dose of their study treatment through 3 injections under the skin
	• The participants got romosozumab or placebo injections once a month for 12 months

What happened during this study?

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

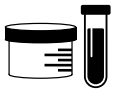
Before joining the study, the participants visited the study clinic 1 time. All the participants fist learned about the study, including potential risks due to the study drug or their participation in the study, and then decided to join. This is called “informed consent”. Then, the study doctors and study staff asked the participants about their medical history and checked their health to make sure they could join the study. The study doctors also checked the participants’ bone density in their spine using an X-ray. This part of the study lasted up to 5 weeks.

During the study, the participants:

Visited the study clinic 13 times

Received study treatment for 12 months

Took Vitamin D and calcium supplements to help with overall bone health



Gave blood and urine samples at some clinic visits

The study doctors:

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

Checked for the participants' bone density and for fractures using X-rays at some clinic visits

Took samples of hip bone from some participants to look at bone tissue

After getting the last treatment, the participants visited the study clinic 1 more time. The study doctors asked about their health and any medical problems they were having. This part of study lasted up to 3 months.

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 below include 236 out of 245 participants. This is because some participants left the study before getting all of their study treatments or measurements.

Did romosozumab increase the participants' bone density in their lower spine?

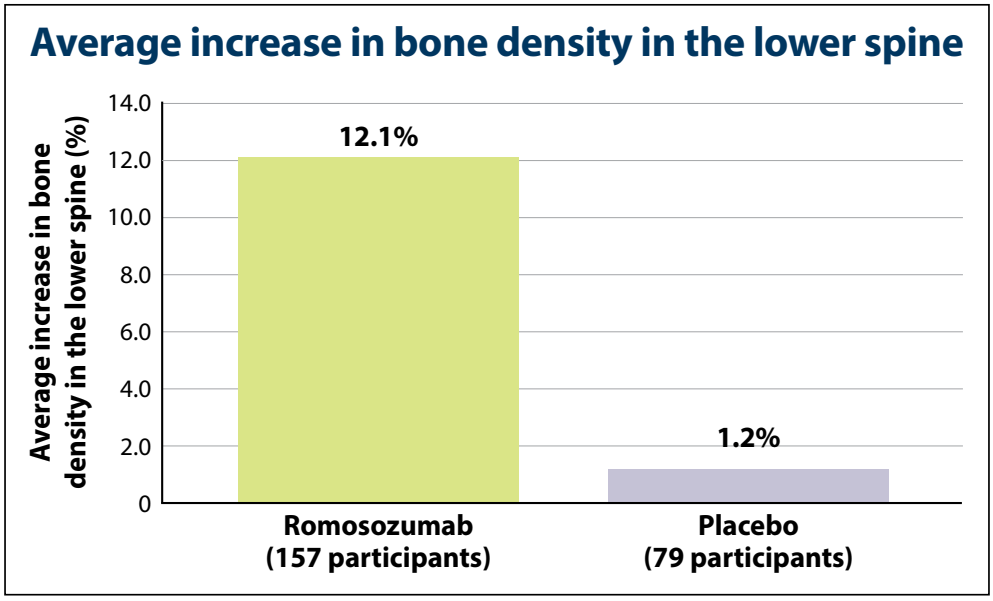
Yes. In this study, bone density in the spine increased more in the participants who were given romosozumab compared to the participants who were given the placebo.

To answer this question, the study doctors used X-rays to measure each participant's bone density in their lower spine. This was measured in units called grams per centimeter squared, also called g/cm^2. The researchers compared the participants' bone density before they were given study treatment and after 12 months of being given study treatment. They calculated the increase in bone density as a percentage.

The researchers found that the average increase in bone density in the lower spine after 12 months of treatment was:

- 12.1% in the participants who got romosozumab
- 1.2% in the participants who got the placebo

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 study doctors thought might be related to the 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 puts the participant’s life at risk, requires hospitalization, causes disability, causes a baby being born with medical problems, or may have turned into 1 of these problems if not treated.

Other studies may or may not show that these adverse reactions were related to the treatments in the study. The final decision about if the treatments actually cause an adverse reaction or not will be based on all the information collected for the treatments and will be shown in the Patient Information Leaflet.

The results below are for 244 participants who got at least 1 dose of study treatment.

How many participants had serious adverse reactions?

None of the participants in this study had serious adverse reactions.

How many participants had any adverse reactions?

Adverse reactions that were serious or not serious happened in:

- 11.7% of participants who were given romosozumab during the study. This was 19 out of 163 participants.
- 8.6% of participants who were given the placebo. This was 7 out of 81 participants.

What adverse reactions did the participants have?

The most common adverse reaction was pain at the site of an injection. The table below shows the adverse reactions that happened in 2.0% or more of participants in a treatment group.

Adverse reactions in 2.0% or more of participants in any treatment group during the study

Adverse reaction	Romosozumab (out of 163 participants)	Placebo (out of 81 participants)
Pain at the site of an injection	2.5% (4)	0.0% (0)
Itchiness at the site of an injection	0.6% (1)	2.5% (2)

How has this study helped patients and researchers?

The results of this study have helped researchers learn more about using romosozumab in men with osteoporosis.

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 study may be used in other studies to compare romosozumab with other treatments for people who have osteoporosis.

At the time this study ended, further clinical studies in with romosozumab in people with osteoporosis were 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/NCT02186171
- www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2013-005551-32

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

Study Information

Protocol Number: 20110174

Study Sponsor: Amgen, Inc.

Full Study Title: A Multicenter, Randomized, Double-blind, Placebo-controlled Study to Compare the Efficacy and Safety of Romosozumab With Placebo in Men With Osteoporosis

National Clinical Study Number: NCT02186171

EudraCT Number: 2013-005551-32

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
Itchiness at the site of an injection	Also called “injection site pruritis”
Pain at the site of an injection	Also called “injection site pain”

This summary was last updated on 13 April 2021.
The final clinical study report is dated 21 April 2016.