Clinical Study Results

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medicine works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer Inc.

Medicine Studied: Tanezumab

Protocol Number: A4091061

Dates of Study: 28 October 2015 to 25 June 2021

Title of this Study: A Study to Learn If Tanezumab Could Lessen Metastatic Bone Pain in Participants Who Were Taking Opioids

[A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of the Analgesic Efficacy and Safety of the Subcutaneous Administration of Tanezumab (PF-04383119) in Subjects With Cancer Pain Predominantly due to Bone Metastasis Receiving Background Opioid Therapy]

Date of this Report: 23 February 2022

– Thank You –

If you participated in this study, Pfizer, the Sponsor, would like to thank you for your participation.

This summary will describe the study results. If you have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What are "bone metastasis" and "metastatic bone pain"?

"Bone metastasis" happens when cancer has spread from its original site to a bone. Bone metastasis is the most common cause of cancer pain.

"Metastatic bone pain" happens when bone metastasis causes pain. Metastatic bone pain is called MBP.

What is tanezumab?

Tanezumab is a study medicine that has not been approved for use in patients. Researchers think it could help lessen MBP. Tanezumab was injected under the skin using a needle.

What was the purpose of this study?

Researchers wanted to know:

Did tanezumab help participants lessen MBP?

MBP can last for a long time and has a negative impact on well-being. While there are treatments for cancer pain, good control of MBP remains a challenge.

Patients who have MBP may need to take "opioids." Opioids are a kind of medicine for pain relief. They are given for pain that is rated as medium to worst. But, opioids alone may give poor control of MBP.

Researchers wanted to learn if tanezumab could lessen MBP in participants who were taking opioids.

What happened during the study?

How was the study done?

At the start of the study, participants were taking an opioid daily for MBP. When they began a study treatment, they kept on taking opioids at the same time.

What were the study treatments?

- Tanezumab 20 mg
- Tanezumab 10 mg
- "Placebo"

A placebo does not have any medicine in it, but it looks just like tanezumab.

The participants and researchers did not know who were given tanezumab and who were given the placebo. This is known as a "blinded" study. Participants were assigned to a group by chance alone.

- **Tanezumab 20 mg group:** 72 participants were given tanezumab 20 mg.
- **Tanezumab 10 mg group:** 9 participants were given tanezumab 10 mg. In the middle of study, the sponsor removed the tanezumab 10 mg group.
- **Tanezumab 10/20 mg group:** 1 participant was first given tanezumab 10 mg, but was later switched to tanezumab 20 mg.
- **Placebo group:** 74 participants were given placebo.

Researchers compared the results of participants taking tanezumab to the results of those taking a placebo.

The figure below shows what happened during the study.

Figure 1. What were the 3 parts of the study?

Screening Period:
Lasted up to 37 days

Study doctors and staff:

- checked the participants' health and did tests to find out who could join the study.
- made sure the opioid dose helped to partly lessen MBP of participants.
- checked if participants could endure the side effects of the opioid dose.

Treatment Period:
Lasted 24 weeks

Participants were given a study treatment once every 8 weeks for a total of 3 times.

Study treatments:

- Tanezumab 20 mg
- Tanezumab 10 mg
- Placebo

Follow-up Period:
Lasted 24 weeks

Participants were no longer taking a study treatment.

They had check-ups by phone calls and clinic visits.

Throughout the study:

Participants took an opioid daily for MBP. They took opioids by mouth or as a skin patch. They kept a record of their pain scores and medicines taken in a diary. They answered survey questions about their MBP.

Study doctors or staff checked the participants' health. They asked participants how they were feeling and what medicines they were taking. They took X-rays of the participants' hips, knees, and shoulders.

Where did this study take place?

The Sponsor ran this study at 48 study sites in 15 countries. The countries were in Asia, Europe, South America, and Australia.

When did this study take place?

It began 28 October 2015 and ended 25 June 2021.

Who took part in this study?

The study included adults who were at least 18 years old. They all had cancer with bone metastasis. The participants were taking an opioid every day to treat MBP. But, opioids gave them poor pain relief.

- A total of 86 men and 69 women took part.
- All participants were between 30 and 86 years old.

Out of 156 participants who started the study:

- 1 participant left the study before starting any study treatment.
- 155 participants were given a study treatment. Out of the 155 participants:
    - 65 participants finished the study.
    - 90 participants did not finish the study. This was because of medical problems, death, or other reasons. Most of the deaths were due to cancer that had gotten worse.

How long did the study last?

Participants were in the study for 48 weeks. The entire study took 5 years and 8 months to complete.

When the study ended in June 2021, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

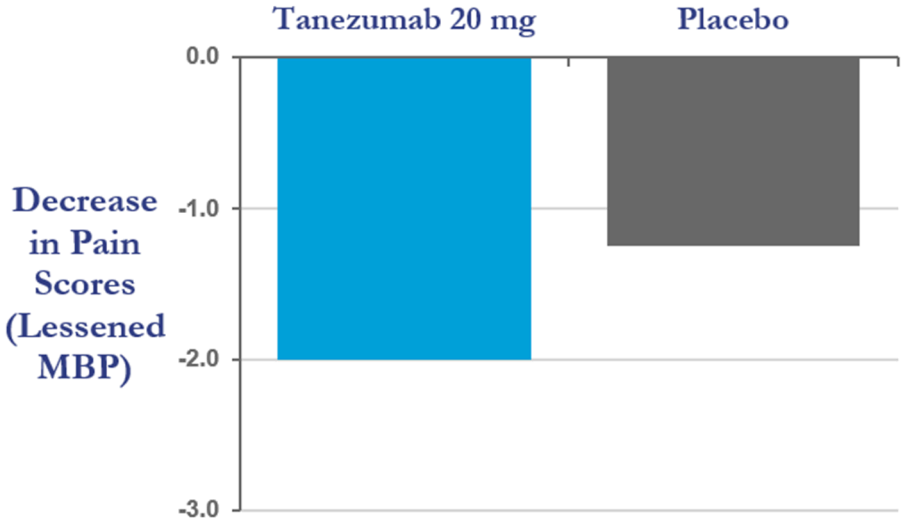
What were the results of the study?

Did tanezumab help participants lessen MBP?

To find out, participants rated their MBP every day on a scale of 0 (no pain) to 10 (worst pain). Then, researchers compared the pain scores before treatment started and after 8 weeks of treatment. Participants were given tanezumab or placebo as a study treatment. They were given a study treatment while taking an opioid at the same time.

The figure below shows the results.

Figure 2. Did tanezumab help to lower the pain score after 8 weeks of treatment compared to placebo?



Participants who were given tanezumab 20 mg (blue bar) had a greater decrease in pain score than those who were given placebo (grey bar).

Researchers reviewed the difference in the results between the tanezumab and placebo groups. They found that tanezumab may help lessen MBP, and these results were not likely due to chance.

This does not mean that everyone in this study had these results. These results are the average of all participants. A study participant may have had a greater or lower decrease in pain when taking study treatment. Similar studies may have different results than the results of this study.

What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study treatment or by another medicine the participant was taking. Sometimes, the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what effects a study medicine might have on a participant.

While being given a study treatment, 112 out of 155 (72%) participants had at least 1 medical problem.

The table below shows the most common medical problems seen in 5 or more participants.

Table 1. What were the most common medical problems?

Medical Problem	Placebo (73 Participants)	Tanezumab 10 mg (9 Participants)	Tanezumab 10/20 mg (1 Participant)	Tanezumab 20 mg (72 Participants)
Low red blood cell counts	9 out of 73 participants (12%)	1 out of 9 participants (11%)	1 out of 1 participant (100%)	6 out of 72 participants (8%)
Pain in joints	6 out of 73 participants (8%)	0 out of 9 participants (0%)	0 out of 1 participant (0%)	6 out of 72 participants (8%)

Table 1. What were the most common medical problems?				
Medical Problem	Placebo (73 Participants)	Tanezumab 10 mg (9 Participants)	Tanezumab 10/20 mg (1 Participant)	Tanezumab 20 mg (72 Participants)
Loss of appetite	2 out of 73 participants (3%)	0 out of 9 participants (0%)	1 out of 1 participant (100%)	6 out of 72 participants (8%)
Prostate cancer that got worse	6 out of 73 participants (8%)	0 out of 9 participants (0%)	1 out of 1 participant (100%)	6 out of 72 participants (8%)
Swelling in the legs or arms	0 out of 73 participants (0%)	0 out of 9 participants (0%)	0 out of 1 participant (0%)	5 out of 72 participants (7%)
Pain	3 out of 73 participants (4%)	0 out of 9 participants (0%)	0 out of 1 participant (0%)	5 out of 72 participants (7%)
Breast cancer that got worse	5 out of 73 participants (7%)	1 out of 9 participants (11%)	0 out of 1 participant (0%)	4 out of 72 participants (6%)
Nausea	5 out of 73 participants (7%)	0 out of 9 participants (0%)	0 out of 1 participant (0%)	4 out of 72 participants (6%)
Vomiting	5 out of 73 participants (7%)	0 out of 9 participants (0%)	1 out of 1 participant (100%)	4 out of 72 participants (6%)
Back pain	7 out of 73 participants (10%)	1 out of 9 participants (11%)	0 out of 1 participant (0%)	1 out of 72 participants (1%)

In total, 15 out of 155 (10%) participants left the study because of medical problems.

Did study participants have any serious medical problems?

A medical problem is considered "serious" when it is life-threatening, needs hospital care, or causes lasting problems.

In the study, 70 out of 155 (45%) participants had serious medical problems.

The table below shows the most common serious medical problems seen in 2 or more participants.

Table 2. What were the most common serious medical problems?

Medical Problem	Placebo (73 Participants)	Tanezumab 10 mg (9 Participants)	Tanezumab 10/20 mg (1 Participant)	Tanezumab 20 mg (72 Participants)
Prostate cancer	7 out of 73 participants (10%)	1 out of 9 participants (11%)	1 out of 1 participant (100%)	7 out of 72 participants (10%)
Lung cancer that got worse	2 out of 73 participants (3%)	0 out of 9 participants (0%)	0 out of 1 participant (0%)	4 out of 72 participants (6%)
Low red blood cell counts	3 out of 73 participants (4%)	0 out of 9 participants (0%)	1 out of 1 participant (100%)	3 out of 72 participants (4%)
Breast cancer that got worse	5 out of 73 participants (7%)	0 out of 9 participants (0%)	0 out of 1 participant (0%)	3 out of 72 participants (4%)
Bone metastases that got worse	1 out of 73 participants (1%)	0 out of 9 participants (0%)	0 out of 1 participant (0%)	3 out of 72 participants (4%)
Colon cancer that got worse	0 out of 73 participants (0%)	0 out of 9 participants (0%)	0 out of 1 participant (0%)	2 out of 72 participants (3%)
Partial paralysis of lower limbs	1 out of 73 participants (1%)	0 out of 9 participants (0%)	0 out of 1 participant (0%)	2 out of 72 participants (3%)
Clot in a blood vessel in the lungs	0 out of 73 participants (0%)	0 out of 9 participants (0%)	0 out of 1 participant (0%)	2 out of 72 participants (3%)
Infection of the lungs	3 out of 73 participants (4%)	0 out of 9 participants (0%)	0 out of 1 participant (0%)	1 out of 72 participants (1%)
Cancer pain	2 out of 73 participants (3%)	0 out of 9 participants (0%)	0 out of 1 participant (0%)	0 out of 72 participants (0%)

A total of 46 out of 155 (30%) participants died during the study. The study doctors judged the deaths as not caused by the study medicine. Most of the deaths were due to cancer that had gotten worse.

Where can I learn more about this study?

If you have questions about the results of your study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit any of the links below.

The full scientific report of this study is available online at:

www.clinicaltrials.gov	Use the study identifier **NCT02609828**
www.clinicaltrialsregister.eu	Use the study identifier **2013-002223-42**
www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **A4091061**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

Again, if you participated in this study,
thank you for volunteering.
We do research to try to find the
best ways to help patients, and you helped
us to do that!