



CLINICAL TRIAL 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(s) Studied: Tanezumab

Protocol Number: A4091057

Dates of Trial: 2 March 2016 to 14 November 2018

Title of this Trial: A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of the Analgesic Efficacy and Safety of the Subcutaneous Administration of Tanezumab in Subjects With Osteoarthritis of the Hip or Knee

Date of this Report: 22 October 2019

– *Thank You* –

Pfizer, the Sponsor, would like to thank you for your participation in this clinical trial and provide you a summary of results representing everyone who participated. If you have any questions about the study or results, please contact the doctor or staff at your study site.

WHY WAS THIS STUDY DONE?

Osteoarthritis is a common disease of the joints that can happen when the cartilage, a protective tissue that covers the joints, begins to wear down over time. This can cause symptoms such as pain, tenderness, stiffness, and loss of flexibility in the affected joints. It can also cause “bone spurs”, or extra pieces of bone, to form around the joints.

There is currently no cure for osteoarthritis, but doctors can prescribe medicines to manage pain and other symptoms. These medicines may not work well for all patients with osteoarthritis, so researchers are looking for additional treatment options. Tanezumab is being studied as a possible treatment option for osteoarthritis. Because it is still being tested, tanezumab has not been approved for use in patients.

The main purpose of this study was to learn more about how tanezumab works to treat osteoarthritis symptoms. The researchers wanted to answer this question:

- Did patients who received tanezumab have an improvement in osteoarthritis symptoms, compared to patients who received placebo?

A placebo does not have any medicine in it, but looks just like the medicine. A placebo is also known as a “dummy drug”.

WHAT HAPPENED DURING THE STUDY?

This study compared 3 groups of patients to find out if patients taking tanezumab would have an improvement in osteoarthritis symptoms. To answer the research question, the researchers looked at 3 smaller questions:

- Change in amount of pain due to osteoarthritis, from before study treatment to week 24 of the study.
- Change in amount of physical difficulty due to osteoarthritis, from before study treatment to week 24 of the study.
- Change in overall functioning, from before study treatment to week 24 of the study.

The study included adult patients with osteoarthritis in the hip or knee, who did not get adequate pain relief from certain other pain medicines, or who were unable or unwilling to take certain other pain medicines.

First, patients were screened by the study doctor to make sure they were appropriate to join the study. This was known as the “screening period”, which lasted up to 37 days. During this time, X-rays of the joints were taken, and osteoarthritis pain was assessed.

The next part of the study was the “treatment period”, which lasted 24 weeks. Patients were assigned to 1 of 3 treatment groups in very similar numbers. Patients were assigned to each group by chance alone. Putting people into groups by chance helps make the groups more similar so they can be compared.

Study treatments were given as an injection under the skin (subcutaneously). Patients received a total of 3 injections during the study, 1 on the first day of the study, a second one at week 8, and a third one at week 16.

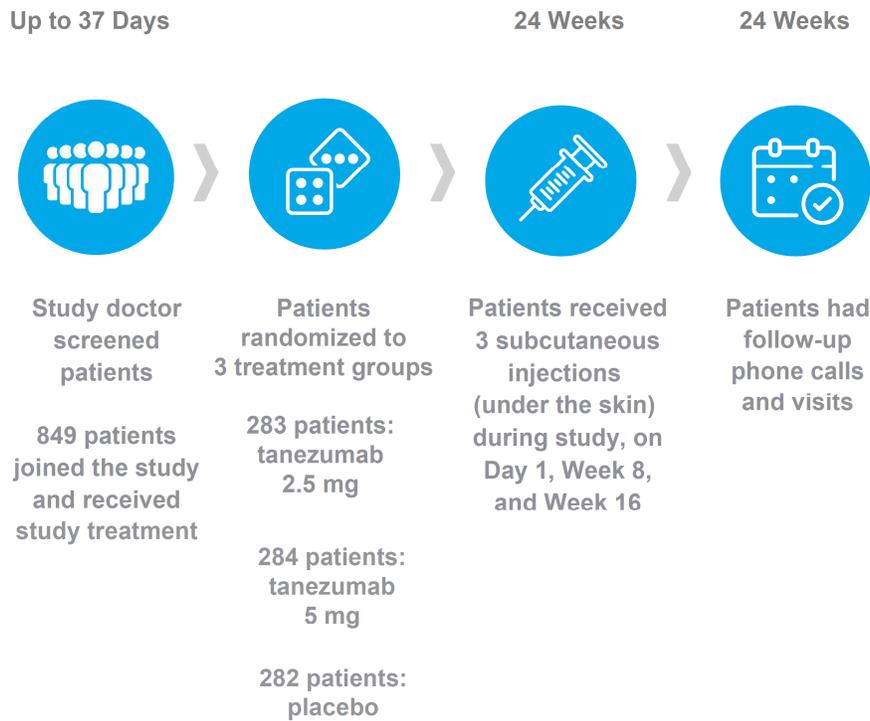
The study treatments included:

- Group 1: Tanezumab 2.5 mg
- Group 2: Tanezumab 5 mg
- Group 3: Placebo

The patients and researchers did not know who took tanezumab and who took the placebo (dummy drug), since all treatment options looked the same. This is known as a “blinded” study.

At study visits in the clinic, starting at the screening visit, the patients completed questionnaires, like the questionnaires about pain from osteoarthritis, physical disability from osteoarthritis, and overall well-being that were used to answer the research question. They also let the staff know about illnesses and discomforts, and had assessments (like physical exam, blood pressure, and more) done by the study doctors and other qualified personnel.

Finally, there was a follow-up period, which lasted 24 weeks. During this time, the study doctors monitored the patients for any medical problems. Patients did not receive study treatments during the follow-up period. The figure below shows what happened during this study.



While patients were only in the study for about 48 weeks, the entire study took about 2 ½ years to complete. The Sponsor ran this study at 104 locations in Europe and Japan. It began 2 March 2016 and ended 14 November 2018. 262 men (31%) and 587 women (69%) participated. All patients were between the ages of 26 and 89.

Patients were to be treated for 24 weeks. Patients were then to complete the 24-week follow-up period, during which time they did not receive study treatments. A total of 849 patients joined the study and received study treatment. Of these patients, 726 (85.5%) finished the study. There were 123 patients (14.5%) who left before the study was over by their choice or a doctor decided it was best for a patient to stop the study.

When the study ended in November 2018, 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 patients who received tanezumab have an improvement in osteoarthritis symptoms, compared to patients who received placebo?

To answer this question, the researchers looked at the patients' questionnaire results rating their osteoarthritis symptoms in 3 areas (pain due to osteoarthritis, physical difficulty due to osteoarthritis, and overall functioning) from before the start of study treatment and from week 24 to see if there was an improvement.

On average, patients who received tanezumab 5 mg had a greater improvement in all 3 areas (pain due to osteoarthritis, physical difficulty due to osteoarthritis, and overall functioning), compared to patients who received placebo. The researchers have decided that these results are not likely a result of chance.

On average, patients who received tanezumab 2.5 mg had a greater improvement in pain due to osteoarthritis and physical difficulty due to osteoarthritis, compared to patients who received placebo. The researchers have decided that these results are not likely a result of chance. Patients in this group also had an improvement in overall functioning, compared to patients who received placebo. However, this result did not show that tanezumab 2.5 mg was better than another treatment. This difference could have been due to chance.

This does not mean that everyone in this study had these results. Other studies may produce different results, as well. These are just some of the main findings of the study, and more information may be available at the websites listed at the end of this summary.

WHAT MEDICAL PROBLEMS DID PATIENTS HAVE DURING THE STUDY?

The researchers recorded any medical problems the patients had during the study. Patients 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 patient 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 the side effects of an experimental drug might be.

During the treatment period, 467 out of 849 patients (55%) had at least 1 medical problem. A total of 8 (1%) patients left the study during the treatment period because of medical problems. The most common medical problems during the treatment period are listed below.

Most Common Medical Problems (Reported by More Than 2% of Patients in Any Treatment Group)			
Medical Problem	Tanezumab 2.5 mg (283 Patients Treated)	Tanezumab 5 mg (284 Patients treated)	Placebo (282 Patients Treated)
Common cold	31 (11%)	22 (8%)	25 (9%)
Joint pain	27 (10%)	23 (8%)	34 (12%)
Back pain	16 (6%)	17 (6%)	15 (5%)
Headache	15 (5%)	14 (5%)	18 (6%)
Fall	12 (4%)	7 (3%)	8 (3%)
Pain in hands or feet	9 (3%)	5 (2%)	7 (3%)
Worsening osteoarthritis	9 (3%)	13 (5%)	5 (2%)
Feeling dizzy	7 (3%)	6 (2%)	2 (1%)

Joint swelling	6 (2%)	8 (3%)	3 (1%)
Pain in the muscles or bones	6 (2%)	7 (3%)	7 (3%)
Urinary tract infection	6 (2%)	2 (less than 1%)	4 (1%)
Flu	5 (2%)	9 (3%)	5 (2%)
Tingling or prickling feeling	5 (2%)	12 (4%)	5 (2%)
Infection of the nose, throat, or airways	5 (2%)	6 (2%)	3 (1%)
Numbness	4 (1%)	6 (2%)	2 (1%)
High blood pressure	2 (1%)	6 (2%)	6 (2%)

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

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

A total of 20 out of 849 patients (2%) in the study had serious medical problems during the treatment period, including 8 patients (3%) who received tanezumab 2.5 mg, 9 patients (3%) who received tanezumab 5 mg, and 3 patients (1%) who received placebo.

3 patients died during the study. 2 of these patients received tanezumab 5 mg and died during the treatment period. The study doctors did not consider these deaths to be related to the study treatment. 1 patient received tanezumab 2.5 mg and died during the follow-up period.

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

www.clinicaltrials.gov

Use the study identifier **NCT02709486**

www.clinicaltrialsregister.eu

Use the study identifier **2013-004508-21**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients. A study with tanezumab in patients who have a different disease is currently ongoing.

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