



CLINICAL TRIAL RESULTS

Sponsor: Pfizer, Inc.

Medicine(s) Studied: PF-06372865

Protocol Number: B7431006

Dates of Trial: 28 October 2014 to 13 August 2015

Title of this Trial: PF-06372865 in Patients with Chronic Low Back Pain

[A Randomized, Double Blind, Placebo- and Active-Controlled, 4 Week, Multi-Center, Parallel Group Study Assessing the Analgesic Effect, Safety and Tolerability of PF-06372865 in Subjects With Chronic Low Back Pain Using Naproxen as Positive Control]

Date of this Report: 14 June 2017

- 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.

This summary of results represents a single trial only.

WHY WAS THIS STUDY DONE?

Chronic low back pain (CLBP) is the second leading cause of disability in the United States. CLBP means having this type of back pain for 12 or more weeks. The reason for the pain can often be hard to tell. Sometimes doctors may be unsure of why the patient has CLBP. This is why the goal of treatment for CLBP is to lower the patient's pain.

Doctors prescribe medicines to patients with CLBP to help decrease the pain. For some, these medicines do not fully work to lower pain. Others may experience side effects associated with these medicines such as bleeding in the stomach or intestines.

Researchers did this study to look for a new way to treat patients with CLBP. PF-06372865 was the medicine tested in this study. PF-06372865 is a medicine that is given as a pill that may help to lower pain in patients with CLBP. For this study, researchers wanted to answer the questions:

- Does PF-06372865 lower pain in patients with CLBP?
- Is PF-06372865 safe for patients with CLBP?

WHAT HAPPENED DURING THE STUDY?

This study compared 3 groups of patients to find out if PF-06372865 helped to lower pain in patients with CLBP compared to patients taking a placebo. A placebo does not have any medicine in it, but looks just like the medicine being tested. This study also wanted to see if PF-06372865 was safe to take. One group got naproxen. Naproxen is known to lower pain in patients with CLBP. Naproxen was used as a positive control (a medicine that is known to work). This was done to see if the study was run successfully. For example, if naproxen worked for pain relief of CLPB in this study, then the study was run successfully. A positive control was also used to compare how well PF-06372865 worked for pain compared to naproxen.

This study included adult men and women who:

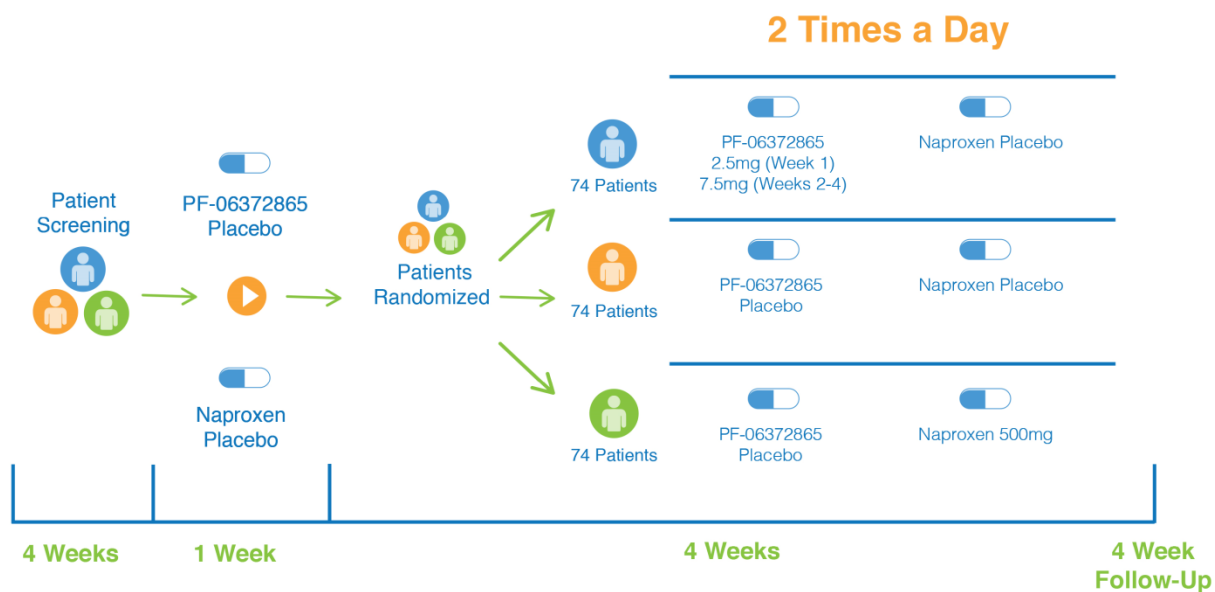
- Had CLBP that:
 - Was ongoing for 3 or more months; and
 - For which the patient took pain medicine (more than just acetaminophen [also known as Tylenol])

Patients were put into 1 of 3 groups by chance alone. This is known as a “randomized” study. This is done to make the groups more similar for things like age, and the number of men and women. Making the groups more similar makes comparing the groups more fair.

The patients and researchers did not know who took what medicine during the study. This is known as a “double-blinded” study. Researchers use “double-blinded” studies to make sure that the results of the study are not influenced in any way.

Descriptions of Medicines Given in Each Group		
Group	Medicines Given	Why the Group Was Used in this Study
1	PF-06372865 2.5 mg (Week 1) then 7.5 mg (Weeks 2 to 4) AND naproxen placebo	To see if PF-06372865 lowered pain
2	PF-06372865 placebo AND naproxen placebo	To see if PF-06372865 lowered pain better than no medicine
3	PF-06372865 placebo AND 500 mg naproxen	To see how well PF-06372865 worked compared to a known pain medicine

For up to 4 weeks, patients were checked (screened) to make sure they met all the requirements to be in the study. Next, all patients took the same placebo treatments for 1 week. The first week of this trial was single-blind. This means that the patient did not know what treatment they were given, but the doctor did know. Then, patients were put into 1 of 3 groups (listed above) and were treated for 4 weeks. After taking the study medicines, patients were followed by researchers for 4 weeks (follow-up phase) to see how they did after taking study medicines. See the study plan below.



While patients were only in the study for 12 weeks (around 3 months), the entire study went on for 10 months. We ran this study at 33 locations in the United States. It began 28 Oct 2014 and ended 13 Aug 2015. 108 men and 114 women participated. All patients were between the ages of 18 and 75.

Patients were supposed to be treated until 4 weeks of treatment. Of the 222 patients who started the study, 188 patients finished the 4 weeks of treatment. 34 patients did not finish 4 weeks of treatment by their choice or a doctor decided it was best for a patient to stop the study. More patients in the placebo group stopped the study early than the PF-06372865 and naproxen groups.

The study was stopped early (before all the planned patients were treated). It was stopped because PF-06372865 did not work well enough. It was not stopped because of safety reasons.

When the study ended in August 2015, 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?

Does PF-06372865 Lower Pain in Patients with CLBP?

In this study, PF-06372865 did not lower pain in patients with CLBP by any more than the placebo. Patients were treated with the study medicines for 4 weeks. During treatment, patients filled out diaries every day. In these diaries the patients recorded how much back pain they had. Researchers then did calculations on this data to look at how pain scores changed. From these calculations, it showed that PF-06372865 had no apparent benefit on pain relief compared to placebo. This study was stopped early because an analysis done during the study showed that PF-06372865 was not working that well to lower pain. The effect of naproxen on pain relief was as expected, so the study was run successfully.

Is PF-06372865 Safe for Patients with CLBP?

Researchers looked at all of the information collected during the study. There were no major safety concerns for PF-06372865 in this study. The most common medical problems due to this medicine were tiredness, dizziness, and nausea. More information about side effects is in the next section.

This does not mean that everyone in this study had these results, and individual result could be better or worse than the overall group. Other studies may find different results. These are just some of the main findings of the study, and more information may be available at the website listed at the end of this summary.

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 have been caused by a study treatment, or by another

drug 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 the side effects of an experimental drug might be.

24 out of 222 patients in this study had at least 1 medical problem. A total of 4 patients (2%, or 4 out of 222 patients) left the study due to medical problems. The most common medical problems are listed in the table below.

Most Common Medical Problems (Reported by More Than 5% of Patients in Any Group)			
Side Effect	PF-06372865 (74 Patients Treated)	Placebo (74 Patients Treated)	Naproxen (74 Patients Treated)
Tiredness	9 (12%)	1 (1%)	1 (1%)
Nausea	6 (8%)	0 (0%)	3 (4%)
Dizziness	6 (8%)	1 (1%)	0 (0%)
Headache	1 (1%)	5 (7%)	1 (1%)

The most common medical problems reported by more patients in the PF-06372865 group than other groups were tiredness, nausea, and dizziness. The placebo group experienced more headaches than the other groups.

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

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

Four patients (2%, or 4 out of 222 patients) had serious medical problems. One patient in the PF-06372865 had a condition that is like a stroke but only lasts a few minutes (transient ischemic attack). This condition does not permanently damage the patient. The researchers considered this related to PF-06372865. 3 patients in the placebo and naproxen groups had a serious side effect. These were not related to the study medicines. No patients died during the study.

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 this study protocol, please visit: www.clinicaltrials.gov (use the study identifier NCT02262754).

No further studies are planned for using PF-06372865 for CLBP. However, other studies with PF-06372865 are planned for patients with other health problems as well as healthy volunteers.

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

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!