



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: Ibuprofen/Acetaminophen

Protocol Number: B5061003

Dates of Trial: 25 September 2015 to 29 June 2016

Title of this Trial: A Phase 3, Double-Blind, Randomized, Safety and Efficacy Study Comparing a Single Oral Dose of Ibuprofen (IBU) 250 mg/Acetaminophen (APAP) 500 mg (Administered as Two Tablets of IBU/APAP 125 mg/250 mg) to Each Active Drug Monocomponent Alone and to Placebo in the Treatment of Post-Surgical Dental Pain

Date of this Report: 13 March 2018

— *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 in this study. 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?

Ibuprofen and acetaminophen are two (2) medications that are commonly used for relieving pain and fever. Both of these medications can be bought without a doctor's prescription ("over the counter"), but they work in slightly different ways. Ibuprofen works by blocking chemicals called "prostaglandins" that the body makes when it is injured or in pain. Researchers think that acetaminophen works by blocking only certain prostaglandins that are found in the nervous system.

Some patients might not get enough pain relief from taking either ibuprofen or acetaminophen alone. Also, taking higher doses of ibuprofen or acetaminophen can cause unwanted medical problems, such as stomach pain or liver problems, without giving patients greater pain relief. Researchers did this study to find out if taking a study drug that combines ibuprofen and acetaminophen together in one (1) tablet could give patients more pain relief than either ibuprofen or acetaminophen alone, without increasing the risk of medical problems.

WHAT HAPPENED DURING THE STUDY?

All the patients in this study had a dental extraction (teeth removed). The researchers divided the patients into four (4) groups, and gave each group a different study treatment. One group took the study drug, which combines ibuprofen and acetaminophen together in one (1) tablet, another group took ibuprofen alone, and another group took acetaminophen alone. Some patients in this study also took a placebo instead of ibuprofen or acetaminophen. A placebo does not have any medicine in it, but looks just like the study treatment. Patients were picked for each treatment group by chance alone. This is known as a "randomized" study, and it helps make the treatment groups more even to compare.

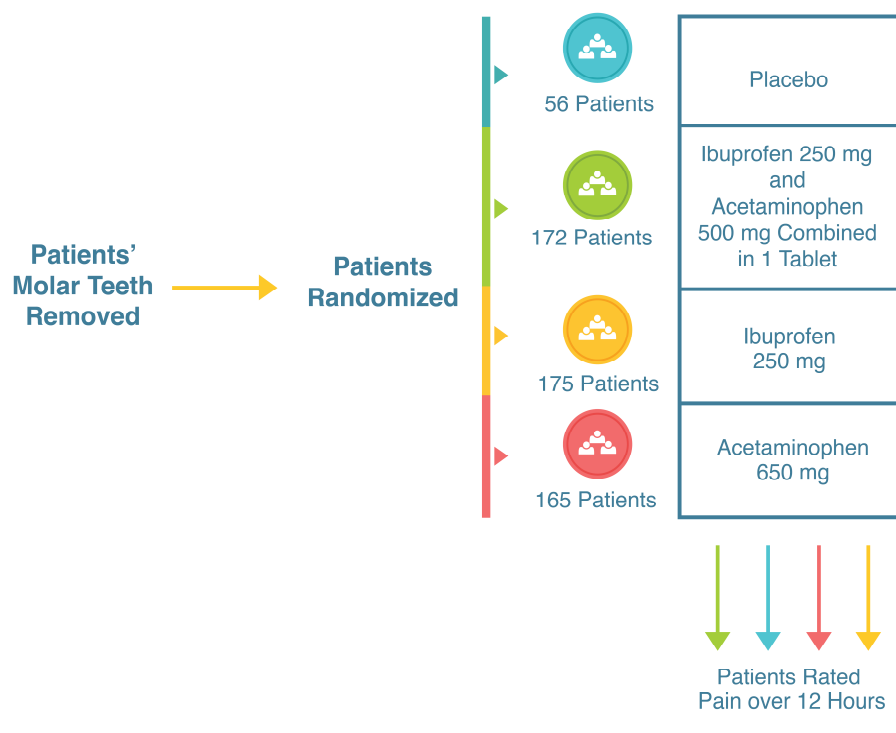
The patients and researchers did not know who took which study treatment, and who took the placebo. This is known as a "double-blind" study. Researchers use this type of study to make sure that the results are not influenced in any way.

After having their teeth removed, the patients rested quietly at the study center for 12 hours. Patients were given their study treatment once they reported having at least moderate pain.

While patients were resting at the study center, researchers asked them to rate their pain 15 times during this study over 12 hours, using a scale of 0 (no pain) to 10 (worst pain). At the end of the study, researchers added together each patient's pain ratings to determine how well their medication worked for treating pain. Researchers also kept track of any medical problems the patients in each group had during the study.

The graph below shows what happened during this study.

What Happened During the Study?



The study included healthy young adults who had at least 3 molar teeth removed. Molar teeth are a type of teeth found in the back of the mouth. All patients were between the ages of 18 and 33 years. 233 men and 335 women participated. While patients were only in the study for 12 hours, the entire study took about nine (9) months to complete. Patients joined the study at one (1) location in the United States. It began 25 September 2015 and ended 29 June 2016. The study was completed as planned.

Of the 568 patients who started the study, 560 completed it. Eight (8) patients left before the study was over by their own choice or because they had a medical problem.

When the study ended in June 2016, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

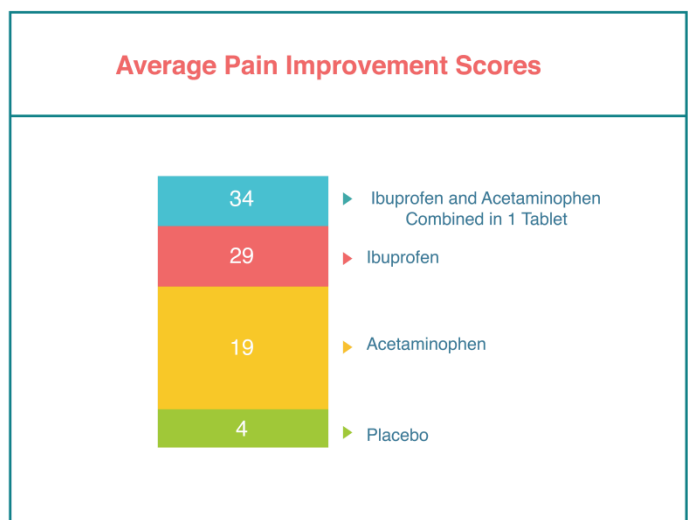
WHAT WERE THE RESULTS OF THE STUDY?

Did patients who took a study drug that combines ibuprofen and acetaminophen together in one (1) tablet have more pain relief after dental extraction, compared to patients who took ibuprofen alone, acetaminophen alone, or placebo?

This trial found that patients who took the study drug had more pain relief than those who took other study treatments. In this trial, patients who had larger pain improvement scores had more pain relief, while patients who had smaller pain improvement scores had less pain relief.

On average, patients who took the study drug that combines ibuprofen and acetaminophen together in one (1) tablet had a pain improvement score of 34, compared to 29 for patients in the ibuprofen only group, 19 for patients in the acetaminophen only group, and 4 for patients in the placebo group. This means that patients who took the study drug had more pain relief, compared to the patients in the other treatment groups. The researchers concluded that these results were not likely the result of chance.

This does not mean that everyone in this study had these results, and individual results 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 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.

A total of 118 out of 568 patients (21%) in the study had at least one (1) non-serious medical problem. One (1) patient left the study due to a medical problem. The most common medical problems are listed below.

Most Common Non-Serious Medical Problems (Reported by At Least 2% of Patients)

Medical Problem	Ibuprofen + Acetaminophen Combined in 1 Tablet (172 Patients)	Ibuprofen Only (175 Patients)	Acetaminophen Only (165 Patients)	Placebo (56 Patients)
Nausea	17 (10%)	24 (14%)	33 (20%)	17 (30%)
Vomiting	7 (4%)	15 (9%)	20 (12%)	11 (20%)
Dizziness	5 (3%)	6 (3%)	12 (7%)	4 (7%)
Headache	0 (0%)	3 (2%)	4 (2%)	0 (0%)
Flushing (Redness)	0 (0%)	2 (1%)	1 (1%)	2 (4%)

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

A medical problem is considered “serious” when it is life-threatening, causes lasting problems, or needs hospital care. No patients in this study had serious medical problems. 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. Findings from this study will be used to seek approval for using this new medication to treat pain and fever.

For more details on this study protocol, please visit:

www.clinicaltrials.gov

Use the study identifier **NCT02912650**

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!