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 medication 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: PF-07261271

Protocol Number: C4631001

Dates of Study: 17 October 2022 to 29 February 2024

Title of this Study: A Study to Learn About the Safety of Single and Multiple Doses of PF-07261271 in Healthy People

[A Phase 1, Randomized, Double-Blind, Sponsor Open, Placebo Controlled, Dose Escalating Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single Intravenous and Multiple Subcutaneous and Intravenous Doses of PF-07261271 in Healthy Participants]

Date(s) of this Report: 13 February 2025

– 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 is inflammatory bowel disease?

Inflammatory bowel disease (IBD) is a condition that involves long-term inflammation (pain and swelling) in the digestive tract. The main symptoms of IBD include diarrhea, stomach ache, blood in stools, feeling tired, and weight loss. Although there are treatment options available for people with IBD, they may not work for everyone.

What is PF-07261271?

The study medication, PF-07261271, is a new type of antibody. An antibody is a protein your body uses to fight off an infection. An antibody can also stop other proteins, which may cause inflammation. PF-07261271 targets 2 proteins that may cause inflammation in people with IBD. PF-07261271 is not yet approved for use.

In this study, PF-07261271 was given as

- a drip into a vein, also known as “intravenous” (IV)
- an injection under the skin, also known as “subcutaneous” (SC).

What was the purpose of this study?

The main purpose of this study was to learn about the safety of different single doses and multiple doses of PF-07261271 in healthy adult participants.

This study did not test if the drug helps to improve IBD or any other disease.

Researchers wanted to know:

- **Did the researchers find any safety concerns in healthy participants who received different doses of PF-07261271?**
- **What medical problems did participants have during the study?**

What happened during the study?

How was the study done?

Researchers tested different doses of PF-07261271 on a group of healthy adult participants to learn about the safety of PF-07261271.

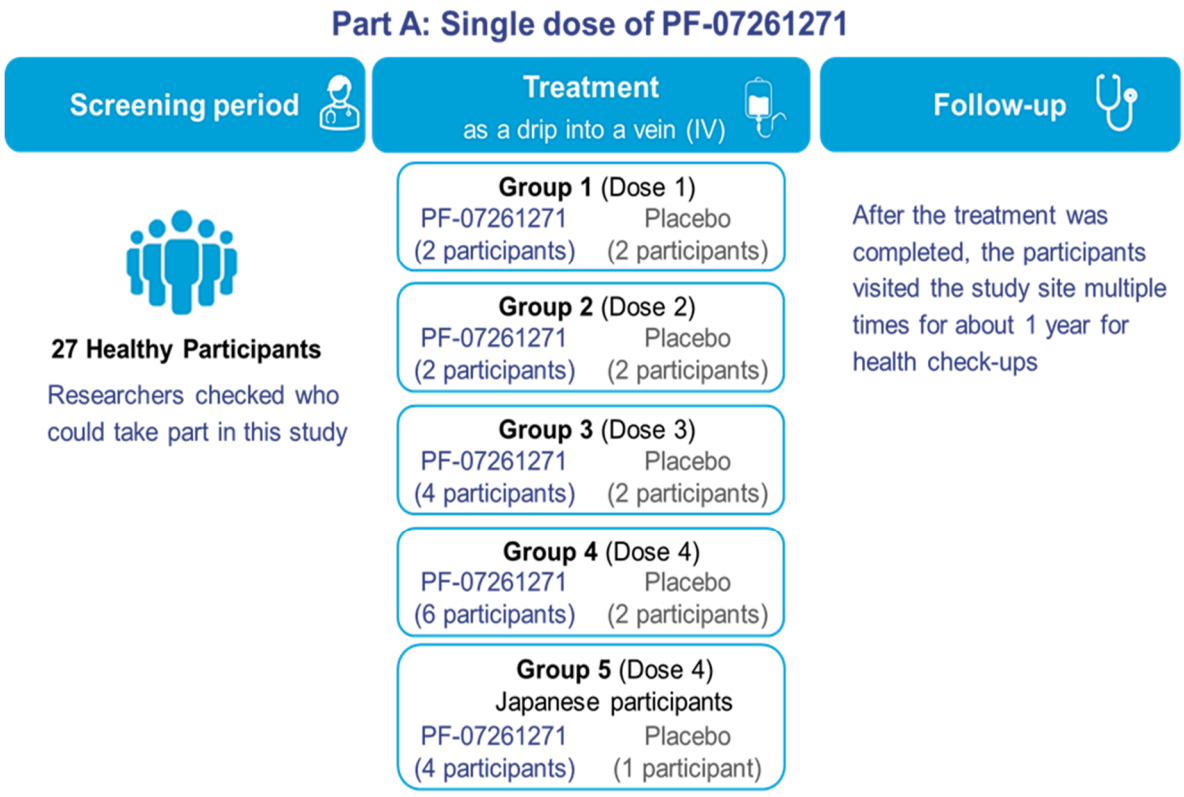
The study was done in 2 parts, Part A and Part B. In Part A, the participants received a single dose of PF-07261271 or "placebo". In Part B, the participants received multiple doses of PF-07261271 or placebo.

A placebo does not have any medicine in it, but it looks just like the study medication. This was done to help researchers try to understand if medical problems that participants had during the study could be related to the study medication or related to something else.

The participants and researchers did not know who took different doses of PF-07261271 and who took the placebo. This is known as a "blinded" study. Participants were assigned to each group by chance alone.

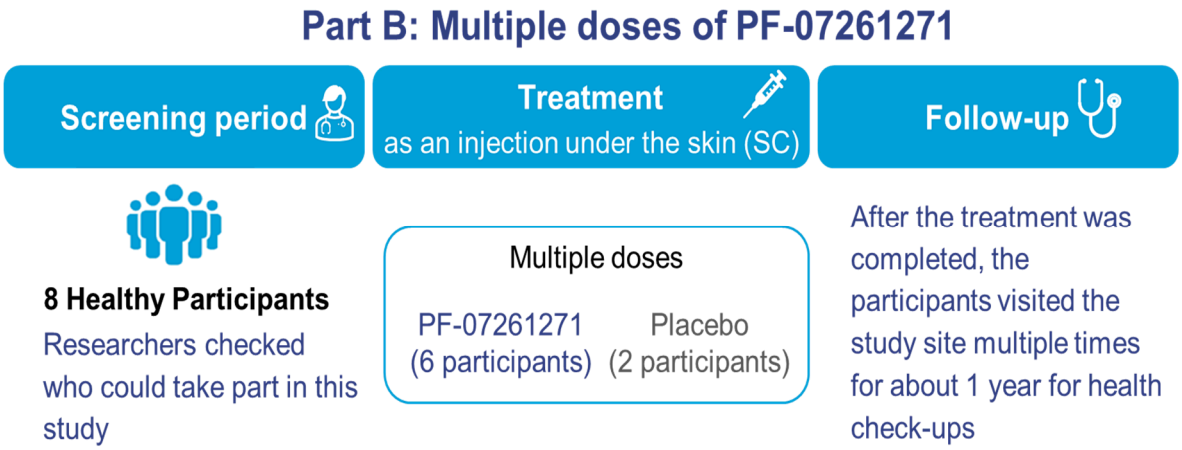
In **Part A**, there were 5 groups. Each group received a dose of PF-07261271 or a placebo. Researchers tested a range of different doses as shown below in figure 1.

Figure 1: What happened during Part A of the study



In **Part B**, there was a single treatment group. The participants received multiple doses of either PF-07261271 or a placebo, as an injection under the skin. Figure 2 on the next page shows what happened during Part B.

Figure 2: What happened during Part B of the study



Researchers checked the participants' health during the study and asked them how they were feeling.

Researchers then compared the results of participants taking different doses of PF-07261271 to the results of participants taking placebo.

Where did this study take place?

The Sponsor ran this study at 3 locations in the United States.

When did this study take place?

It began on 17 October 2022 and ended on 29 February 2024.

Who participated in this study?

The study included healthy participants. Each participant passed certain tests, procedures, and assessments during the screening period.

- A total of 25 men participated.
- A total of 10 women participated.
- All participants were between the ages of 22 and 62 years.

Of the 35 participants who started the study treatment, 34 finished the treatment. One participant did not finish the treatment because of a medical problem. This medical problem was not related to the study medication.

How long did the study last?

Study participants were in the study for a little more than 1 year. The entire study took about 1 year and 5 months to complete.

The Sponsor (some selected individuals) had been reviewing the data since the study began and a report of the results was created by the Sponsor when the study ended in February 2024. This is a summary of that report.

What were the results of the study?

Did the researchers find any safety concerns in healthy participants who received different doses of PF-07261271?

To answer this question, researchers looked at the results of blood and other laboratory tests, vital signs (blood pressure, heart rate, and body temperature) and electrocardiogram (ECG) tests. An ECG is a test of the heart's activity.

This study found that single and multiple doses of PF-07261271 were generally safe and tolerated by healthy participants. The researchers found that overall, the test results did not raise any safety concerns when participants received different doses of PF-07261271, either as a single dose as a drip into the vein or as multiple doses as an injection under the skin.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

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 unknown 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 medication might have on a participant.

In this study, 12 out of 27 (44%) participants in Part A and 7 out of 8 (88%) participants in Part B had at least 1 medical problem. One (1) participant left the study because of medical problem. For Part A, the most common medical problems – those reported by more than 20% of participants – are described below in Table 1. For Part B, the most common medical problems – those reported by more than 30% of participants – are described later in Table 2.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by more than 20% participants are listed.
- The **2nd** column tells how many of the 18 participants who received the study medication reported each medical problem. Next to this number is the percentage of the 18 participants who received the study medication and reported the medical problem.
- The **3rd** column tells how many of the 9 participants who received a placebo reported each medical problem. Next to this number is the percentage of the 9 participants who received a placebo and reported the medical problem.
- Using these instructions, you can see that 1 out of the 18 (6%) participants who received the study medication reported headache. A total of 2 out of the 9 (22%) participants who received a placebo reported headache.

Part A

Table 1. Commonly reported medical problems by study participants in Part A		
Medical Problem	**PF-07261271 (IV) (18 Participants)**	**Placebo (IV) (9 Participants)**
Headache	1 out of 18 participants (6%)	2 out of 9 participants (22%)
Increase in liver enzyme	0	2 out of 9 participants (22%)

Part B

Table 2. Commonly reported medical problems by study participants in Part B		
Medical Problem	**PF-07261271 (SC) (6 Participants)**	**Placebo (SC) (2 Participants)**
Reaction at the injection site	4 out of 6 participants (67%)	1 out of 2 participants (50%)
Abnormal or irregular heartbeat	0	1 out of 2 participants (50%)
Diarrhea and vomiting	0	1 out of 2 participants (50%)

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.

None of the participants had a serious medical problem.

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:

www.pfizer.com/research/research_clinical_trials/trial_results

Use the protocol number **C4631001**

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

www.clinicaltrials.gov

Use the study identifier **NCT05536440**

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!