Plain Language Clinical Study

Summary

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: PF-07264660

Protocol Number: C4521001

Dates of Study: 16 August 2022 to 06 May 2024

Title of this Study: A Study to Learn About the Safety of Single and Multiple Doses of PF-07264660 in Healthy Participants

[A Phase 1, Randomized, Double-Blind, Sponsor-Open, Placebo-Controlled, Dose-Escalating Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single and Multiple Intravenous and Subcutaneous Doses of PF-07264660 in Healthy Participants]

Date of this Report: 03 April 2025

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– 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. Do you have any questions about the study or the results? If so, please contact the doctor or staff at your study site.

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Why was this study done?

What is atopic dermatitis?

Atopic dermatitis (AD) is a common, long-lasting skin condition that affects both children and adults. AD weakens the protective outer layer of the skin. This allows germs to grow, causing skin irritation, and increasing water loss from the skin. This results in periodic flare-ups of red and itchy skin.

The main symptoms of AD includes dry and cracked skin, itchiness, and thickened skin. Although there are treatment options available, there is still a need for safer and more effective treatments that can work on the reasons that cause AD.

What is PF-07264660?

The study medicine, PF-07264660, is a new type of antibody. An antibody is a protein your body uses to fight off an infection. An antibody can also block other proteins that cause inflammation. PF-07264660 targets 3 proteins that may cause inflammation in people with AD. PF-07264660 is not yet approved for treatment in any country.

In this study, PF-07264660 was given as:

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

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What was the purpose of this study?

The main purpose of this study was to learn about the safety and tolerability of different single doses and multiple doses of PF-07264660 in healthy adult participants. "Tolerability" means how well participants can tolerate receiving the study medicine.

This study did not test if the medicine helps to improve AD or any other disease.

Researchers wanted to know:

- **Did the researchers find any safety concerns in healthy participants who received different doses of PF-07264660?**
- **What medical problems did participants have during the study?**

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What happened during the study?

How was the study done?

Researchers tested different doses of PF-07264660 in multiple groups of healthy adult participants to learn about the safety of PF-07264660.

This study was done in 2 parts, Part A and Part B. In Part A, each participant received a single dose of PF-07264660 or "placebo". In Part B, the participants received multiple doses of PF-07264660 or placebo.

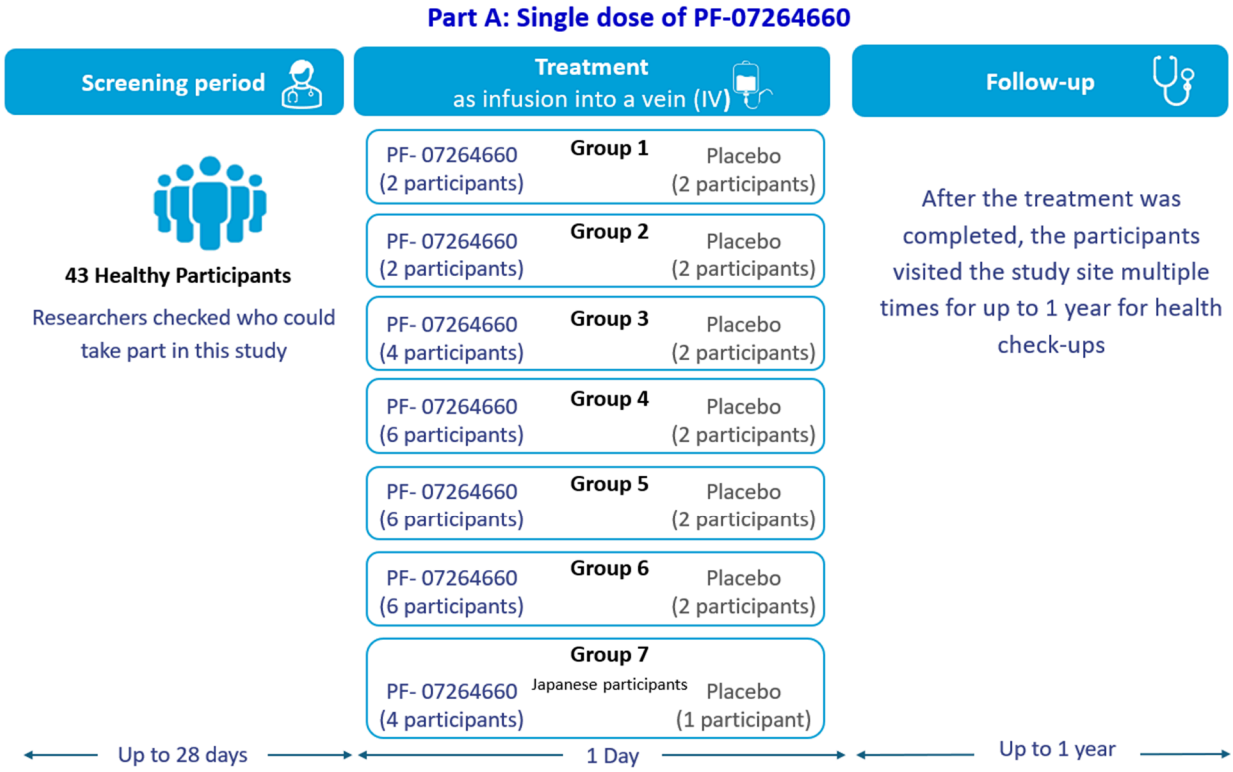
A placebo does not have any medicine in it, but it looks just like the study medicine. This was done to help researchers try to understand if medical problems that participants had during the study could be related to the study medicine or related to something else.

The participants and researchers did not know who received different doses of PF-07264660 and who received the placebo. This is known as a "blinded" study. Participants were assigned to each group by chance alone. This is known as "randomization".

In **Part A**, there were 7 groups. Each group received a single dose of PF-07264660 or placebo as an IV infusion. The Figure 1 below shows what happened during Part A.

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Figure 1: What happened during Part A?

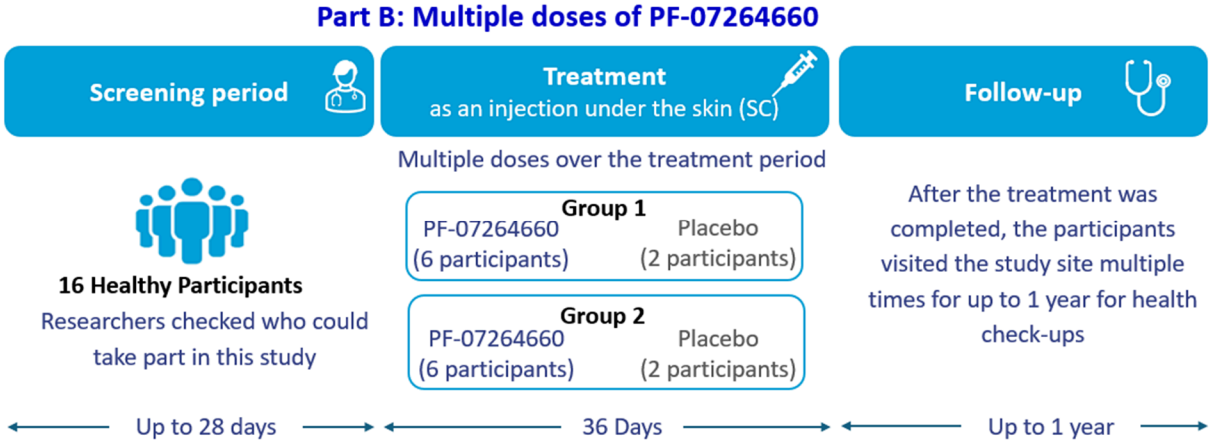


In **Part B**, there were 2 groups. The participants received multiple doses of PF-07264660 or placebo.

Figure 2 below shows what happened during Part B.

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Figure 2: What happened during Part B?



Participants visited the study site after their last dose for up to 1 year. During these visits, the researchers collected blood samples for laboratory tests and carried out health checks.

Researchers compared the results from study participants in each treatment group.

Researchers checked the participants' health throughout the study.

Where did this study take place?

The Sponsor ran this study at 4 locations in the United States.

When did this study take place?

It began 16 August 2022 and ended 06 May 2024.

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Who participated in this study?

The study included healthy adult participants with a body mass index (a measure of body weight in relation to height) of 17.5 to 32 kilograms per square meter (kg/m^2) and weighing more than 50 kg.

- A total of 28 men in participated.
- A total of 31 women participated.
- All participants were between the ages of 22 years and 62 years.

Participants were in the study until there were low amounts of PF-07264660 in the blood to check for any safety concerns. Of the 43 participants in Part A, 41 finished the study. Of the 16 participants in Part B, 15 finished the study.

Three (3) participants did not finish the study because:

- They lost to follow-up,
- Had a medical problem, or
- Of other reasons.

How long did the study last?

Study participants were in the study for about one year. The entire study took about 1 year and 9 months to complete.

The Sponsor monitored the data continuously during the study. When the study ended in May 2024, the Sponsor began reviewing all the information collected on both PF-07264660 and placebo. The Sponsor then created a report of the results. This is a summary of that report.

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What were the results of the study?

Did the researchers find any safety concerns in healthy participants who received different doses of PF-07264660?

To answer this question, researchers looked at the results from physical examination, blood and other laboratory tests, vital signs (blood pressure, heart rate, and body temperature), electrocardiogram (ECG) tests, and reports of undesirable effects experienced by participants. An ECG is a test of the heart's activity that looks at how well the heart is working.

This study found that single and multiple doses of PF-07264660 were generally well-tolerated by healthy participants with an overall acceptable safety profile. Overall, the researchers did not find any safety concerns when PF-07264660 was given as a single dose through infusion into the vein, or as multiple doses as an injection under the skin.

The above reported information 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.

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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.

Part A

In Part A, 19 out of 30 participants (63%) who received different doses PF-07264660, and 4 out of 13 participants (31%) who received placebo, had at least 1 medical problem. No participants left the study during Part A because of medical problems. The most common medical problems – those reported by 2 or more participants – are described below in Table 1.

Part B

In Part B, 10 out of 12 participants (83%) who received different doses PF-07264660, and 2 out of 4 participants (50%) who received placebo, had at least 1 medical problem. No participants left the study during Part B because of medical problems. The most common medical problems – those reported by 2 or more participants – are described below in Table 2.

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Below are instructions on how to read Table 1 and Table 2.

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 2 or more participants are listed.
- The **2nd** column tells how many of the 30 participants taking the study medicine reported each medical problem. Next to this number is the percentage of the 30 participants taking the study medicine who reported the medical problem.
- The **3rd** column tells how many of the 13 participants taking the placebo reported each medical problem. Next to this number is the percentage of the 13 participants taking the placebo who reported the medical problem.
- Using these instructions, you can see that 3 out of the 30 (10%) participants who took the study medicine reported bleeding at the site of the infusion. No participant who took the placebo reported bleeding at the site of the infusion.

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Table 1. Commonly reported medical problems by study participants (Part A)		
Medical Problem	**All doses of PF-07264660 (30 Participants)**	**Placebo (13 Participants)**
Bleeding at the site of the infusion	3 out of 30 participants (10%)	0 out of 13 participants (0%)
Reddening of the skin at the site of infusion	3 out of 30 participants (10%)	0 out of 13 participants (0%)
Headache	2 out of 30 participants (7%)	0 out of 13 participants (0%)
Increase in the levels of a liver enzyme called alanine aminotransferase	2 out of 30 participants (7%)	0 out of 13 participants (0%)
Increase in the levels of a liver enzyme called aspartate aminotransferase	2 out of 30 participants (7%)	0 out of 13 participants (0%)
Infection of the parts of the body that collect and pass out urine	2 out of 30 participants (7%)	0 out of 13 participants (0%)
Joint pain	2 out of 30 participants (7%)	1 out of 13 participants (8%)

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Table 1. Commonly reported medical problems by study participants (Part A)		
Medical Problem	All doses of PF-07264660 (30 Participants)	Placebo (13 Participants)
Sleepiness	2 out of 30 participants (7%)	0 out of 13 participants (0%)

Table 2. Commonly reported medical problems by study participants (Part B)		
Medical Problem	All doses of PF-07264660 (12 Participants)	Placebo (4 Participants)
Reaction at the injection site	5 out of 12 participants (42%)	1 out of 4 participants (25%)
Headache	3 out of 12 participants (25%)	0 out of 4 participants (0%)
Itchy skin	3 out of 12 participants (25%)	0 out of 4 participants (0%)
Nose and throat infection	3 out of 12 participants (25%)	0 out of 4 participants (0%)

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Table 2. Commonly reported medical problems by study participants (Part B)		
Medical Problem	**All doses of PF-07264660 (12 Participants)**	**Placebo (4 Participants)**
Skin redness	3 out of 12 participants (25%)	0 out of 4 participants (0%)
Tenderness	3 out of 12 participants (25%)	0 out of 4 participants (0%)
Feeling sick	2 out of 12 participants (17%)	0 out of 4 participants (0%)
Swelling	2 out of 12 participants (17%)	0 out of 4 participants (0%)

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 serious medical problems.

No participants died during the study.

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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 **C4521001**

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

www.clinicaltrials.gov — Use the study identifier **NCT05496738**

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!

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