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(s) Studied:	PF-07202954
Protocol Number:	C4171001
Dates of Study:	13 May 2021 to 17 September 2021
Title of this Study:	Study in Healthy Adults Evaluating PF-07202954 [A Phase 1, 3-Part, Sponsor Open Study of PF-07202954 in Healthy Adults: Randomized, Double-Blind, Placebo-Controlled to Assess Safety, Tolerability and Pharmacokinetics of Single (in Part 1), and Repeated (in Part 2), Escalating, Oral Doses Along With Conditional Part 3 of Randomized, Open-Label Assessment of Effect of Food on PF-07202954 Exposure]
Date(s) of this Report:	08 September 2022

– 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 nonalcoholic steatohepatitis with liver fibrosis?

Nonalcoholic steatohepatitis, or NASH, is liver damage caused by inflammation of the liver and the buildup of fat in the liver ("fatty liver disease"). As NASH progresses, it may cause increasing scarring of the liver. This scarring of the liver is known as cirrhosis. A common complication of cirrhosis is hepatocellular carcinoma or liver cancer. NASH is a specific type of nonalcoholic fatty liver disease (NAFLD) that may increase the risk of death, cirrhosis, and liver disease, as well as liver-related and non-liver-related cancers.

What is PF-07202954?

PF-07202954 is an investigational drug. It is being developed to treat people with NASH and scarring of the liver. Investigational means that PF-07202954 is not approved by the United States Food and Drug Administration (FDA). In this study, PF-07202954 was provided as a liquid. The liquid was swallowed once a day in the morning. This study was the first time PF-07202954 was given to people.

What was the purpose of this study?

The researchers wanted to know if PF-07202954 was safe and well tolerated when given as single, increasing doses, to healthy adult participants.

Researchers wanted to know:

- **How safe and well tolerated were single, increasing doses of PF-07202954?**
- **What medical problems did participants have during the study?**

What happened during the study?

How was the study done?

Researchers tested single, increasing doses of PF-07202954 in a group of healthy adult participants. The researchers did this to learn about the safety and tolerability of PF-07202954.

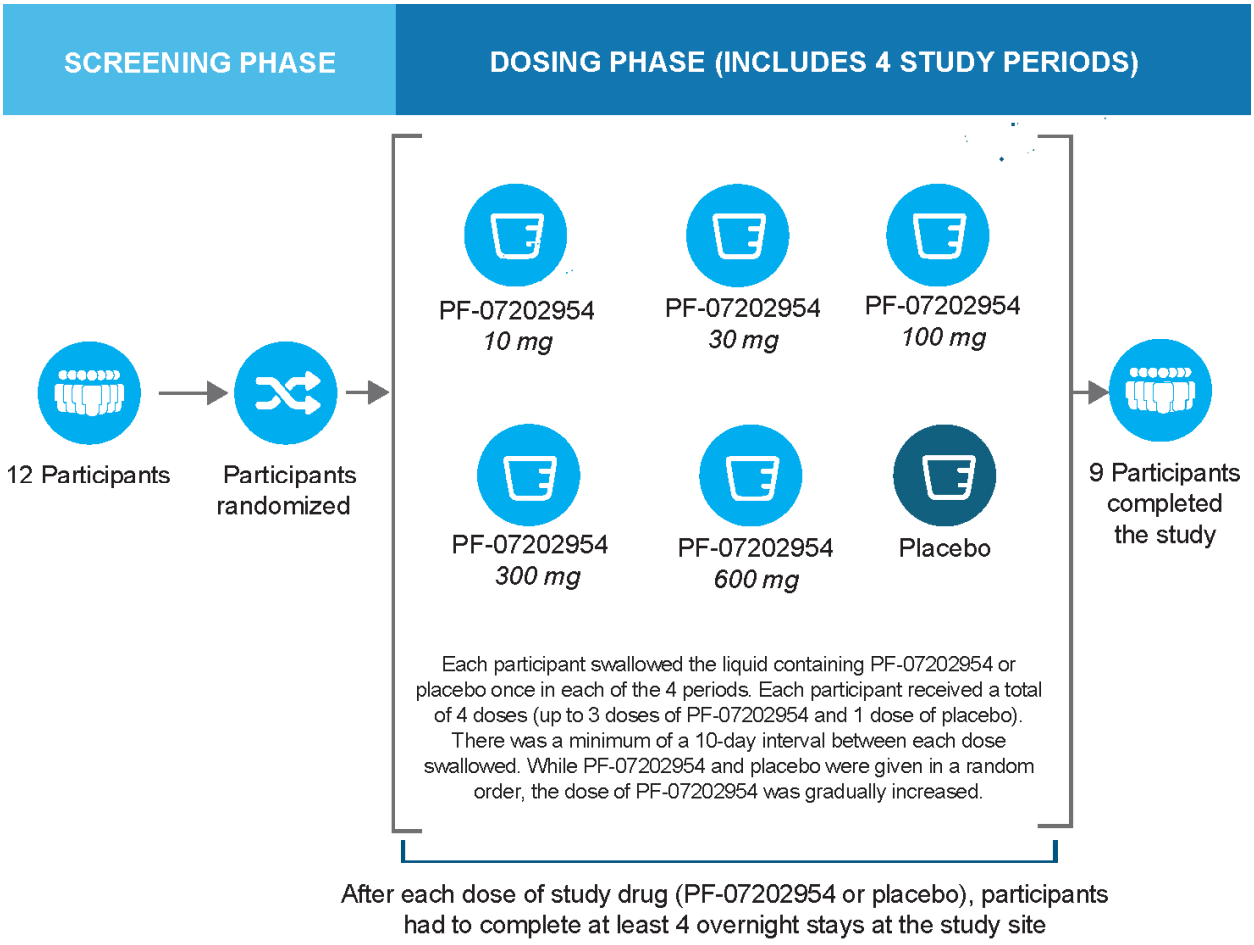
Participants were to swallow the liquid containing PF-07202954 or placebo once in each of the 4 periods. This was after an overnight fast of 10 hours. Participants had to spend at least 4 days at the study center after each dose. Each participant received a total of 4 doses (up to 3 doses of PF-07202954 and 1 dose of placebo). There was a minimum of a 10-day interval between each dose swallowed. A placebo does not have any medicine in it, but it looks just like the study medication (ie, PF-07202954). The PF-07202954 doses tested were 10 mg, 30 mg, 100 mg, 300 mg, and 600 mg. Researchers did this to try to understand if medical problems during the study were related to PF-07202954 or to something else.

While PF-07202954 and placebo were given in a random order, the dose of PF-07202954 was gradually increased. Participants were assigned to each group by chance alone. The participants and researchers did not know who took the different doses of PF-07202954 and who took the placebo. This is known as a "blinded" study. Some participants were also given a high fat/high calorie meal with the study drug. Some participants took the study drug with only water.

Researchers took samples of blood and urine from participants during the study for safety tests. Researchers checked the participants' health during the study and asked them how they were feeling. They did this at a follow-up visit and also by phone call 4 weeks after the last dose of study drug.

Researchers compared the results after participants had taken different doses of PF-072020954 and placebo.

Figure 1 shows the study plan.



The researchers planned to look at repeated doses of PF-07202954 in Part 2. They also wanted to look at the effect of food on the behavior of PF-07202954 in the body in Part 3. Parts 2 and 3 were not conducted.

Where did this study take place?

The Sponsor ran this study at a single location in the United States of America.

When did this study take place?

It began 13 May 2021 and ended 17 September 2021.

Who participated in this study?

The study included healthy adult participants.

- A total of 9 men participated
- A total of 3 women participated
- All participants were between the ages of 23 and 44 years

Of the 12 participants who started the study, 9 participants received both PF-07202954 and placebo and completed the study as planned. There were 3 participants who left the study early because they were no longer able to participant in the study:

- Two participants each received 2 doses of PF-07202954 and 1 dose of placebo, but missed a further dose of PF-07202954
- One participant received 2 doses of PF-07202954, but missed a further dose of PF-07202954 and of placebo

How long did the study last?

Study participants were in the dosing phase of the study for approximately 2 ½ months. The entire study, from the time of consent to the last follow-up, took a little more than 4 months to complete. After Part 1 of the study was completed, the Sponsor decided to end the study early for reasons not related to safety.

When the study ended in September 2021, 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?

How safe and well tolerated were single, increasing doses of PF-07202954?

In this study, the researchers evaluated the safety and tolerability of single, increasing doses of PF-07202954 when given with breakfast and when given on an empty stomach. The researchers did this by looking at the medical problems that participants had during the study. They also looked at the results of laboratory tests, blood pressure, pulse rate, and electrocardiogram (ECG) tests. An ECG is a machine that looks at how well the heart is working when it pumps blood around the body. The next section of this document discusses medical problems in full.

What was the result of laboratory tests after participants had taken single, increasing doses of PF-07202954?

- There were 10 out of the 12 (83%) participants who had abnormal laboratory test results during the study. None of these laboratory abnormalities were thought by the researchers to be clinically significant or considered as medical problems.

What was the result of the blood pressure and pulse rate tests after participants had taken single, increasing doses of PF-07202954?

- There were 3 out of the 12 (25%) participants who had abnormal blood pressure measurements. Two of these instances occurred after placebo and 1 occurred after PF-07202954. The researchers did not think the increased blood pressure was due to the study drug.

What was the result of the ECG tests after participants had taken single, increasing doses of PF-07202954?

- None of the 12 (0%) participants had ECG results that were thought by the researchers to be clinically significant or considered as medical problems.

What medical problems were seen after participants had taken single, increasing doses of PF-07202954?

- This is discussed fully in the next section of this document.

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. No other studies are planned for PF-07202954.

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.

Eight out of 12 (67%) participants in this study had at least 1 medical problem. None of the 12 participants left the study because of medical problems. Table 1 lists all medical problems that were reported after each treatment (PF-07202954 or placebo).

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 reported during the study. All medical problems reported are listed.
- The **2nd** column tells how many of the 11 participants after taking placebo reported each medical problem. Next to this number is the percentage of the 11 participants taking placebo who reported the medical problem.
- The **3rd** column tells how many of the 4 participants after taking 30 mg PF-07202954 reported each medical problem. Next to this number is the percentage of the 4 participants taking 30 mg PF-07202954 who reported the medical problem.
- The **4th** column tells how many of the 9 participants after taking 100 mg PF-07202954 reported each medical problem. Next to this number is the percentage of the 9 participants taking 100 mg PF-07202954 who reported the medical problem.
- The **5th** column tells how many of the 5 participants after taking 300 mg PF-07202954 reported each medical problem. Next to this number is the percentage of the 5 participants taking 300 mg PF-07202954 who reported the medical problem.
- The **6th** column tells how many of the 5 participants after taking 100 mg PF-07202954 with a high fat/high calorie meal reported each medical problem. Next to this number is the percentage of the 5 participants taking 100 mg PF-07202954 with a high fat/high calorie meal who reported the medical problem.

- Using these instructions, you can see that 1 out of the 11(9%) participants after taking placebo reported blood shot eye or eyes. No participants after taking PF-07202954 reported blood shot eye or eyes.

Table 1. Medical problems reported by study participants

Medical problem	Placebo (11 Participants)	PF-07202954 30 mg (4 Participants)	PF-07202954 100 mg (9 Participants)	PF-07202954 300 mg (5 Participants)	PF-07202954 100 mg after high fat/high calorie meal (5 Participants)
Blood shot eye(s)	1 out of 11 participants (9%)	0	0	0	0
Frequent bowel movements	0	0	0	0	1 out of 5 participants (20%)
Nausea	0	0	0	1 out of 5 participants (20%)	1 out of 5 participants (20%)
Mouth irritation	1 out of 11 participants (9%)	1 out of 4 participants (25%)	0	0	0
Pain during the study procedures	1 out of 11 participants (9%)	0	0	0	0
Swollen glands	0	0	1 out of 9 participants (11%)	0	0

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Medical problem	**Placebo (11 Participants)**	**PF-07202954 30 mg (4 Participants)**	**PF-07202954 100 mg (9 Participants)**	**PF-07202954 300 mg (5 Participants)**	**PF-07202954 100 mg after high fat/high calorie meal (5 Participants)**
Pins and needles sensation	0	1 out of 4 participants (25%)	0	0	0
Feeling sleepy	0	0	1 out of 9 participants (11%)	0	0
Painful periods (menstrual cramps)	0	0	1 out of 9 participants (11%)	0	1 out of 5 participants (20%)
Irregular periods	1 out of 11 participants (9%)	0	0	0	0
Breathing symptoms	0	0	1 out of 9 participants (11%)	0	0

No participants reported medical problems after taking 10 mg and 600 mg PF-07202954, or when 100 mg PF-07202954 was given without food (eg, on an empty stomach).

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.

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.

No participants (0%) had serious medical problems in this study. No participants 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 your study protocol, please visit:

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

www.clinicaltrials.gov
Use the study identifier N**CT04857437**

www.pfizer.com/research/research_clinical_trials/trial_results
Use the protocol number C4171001

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!