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 study participants. 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-07304814

Protocol Number: C4611003

Dates of Study: 07 October 2021 to 10 December 2021

Title of this Study: A Study to Determine the Movement of Radiolabelled PF-07304814 Through the Body in Healthy Participants

[A Phase 1, Open-Label, Single-Dose Study to Investigate the Mass Balance, Metabolism and Excretion of [^{14}C]-PF-07304814 in Healthy Participants Using a ^{14}C-Microtracer Approach]

Date(s) of this Report: 29 November 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 COVID-19?

corona**vi**rus **d**isease of 20**19** (COVID-19) is an infection that affects the nose, throat, and lungs. It is caused by a type of virus called the coronavirus. People who are infected by this virus can have mild to very severe symptoms. Some people may have no symptoms at all, while others can have severe symptoms of lung infection. Sometimes people with this infection may even lose their life.

What is PF-07304814?

PF-07304814 is a new investigational drug that is given to patients intravenously (by injection in the vein). This drug has not yet been approved for use by health authorities. PF-07304814 blocks a specific enzyme (protein) called "severe acute respiratory syndrome coronavirus 2. (SARS-COV-2) 3CL." This protein is essential for the virus to multiply and grow. By decreasing the amount of virus in the body, PF-07304814 may help treat COVID-19 infection.

What was the purpose of this study?

The purpose of this study was to find out how much PF-07304814 was in the participants' blood, urine, and feces after they took a "radiolabeled" form of PF-07304814. A radiolabel is a radioactive particle attached to a drug that lets scientists measure the amount of study drug in the body. PF-07304814 is a "pro-drug". A pro-drug is a substance that the body breaks down into an active drug.

When PF-07304814 is injected, it enters the blood and organs (for example, stomach, liver, and kidneys) when it moves through the body. Afterwards, PF-07304814 is removed from the body through urine and feces.

This study did not test to see if the drug helps to improve COVID-19 symptoms.

Researchers wanted to know:

- **How much radiolabeled PF-07304814 was found in the urine and feces of participants during the study?**
- **How PF-07304814 entered and moved through the body and how long it stayed in the body?**

What happened during the study?

How was the study done?

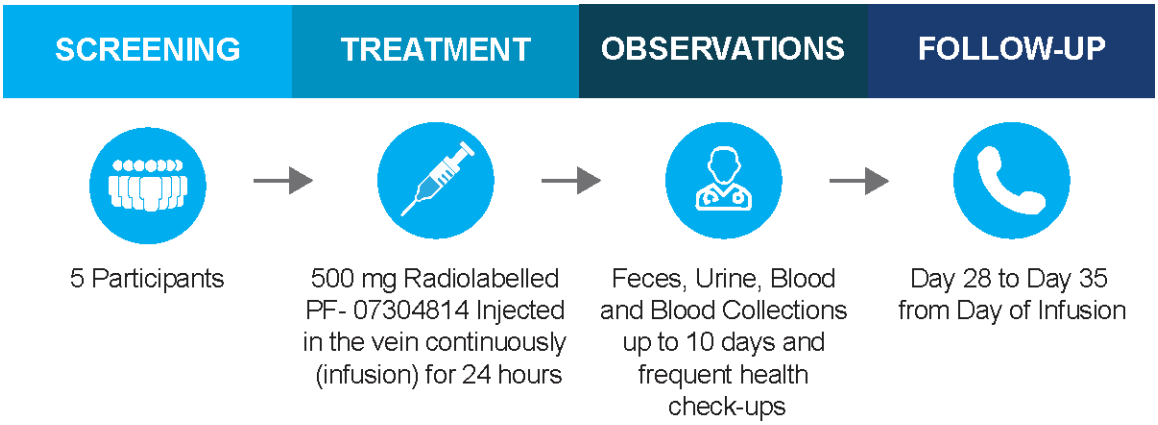
This was an open-label study. That means, both the researchers and the participants knew what medication was being given. Participants were given a single dose of PF-07304814 containing a radiolabel.

Researchers tested one dose of radiolabelled PF-07304814 on a group of healthy participants to learn how PF-07304814 acted in the body.

Participants were given 500 milligrams of PF-07304814 containing the radiolabel as a continuous infusion (injection into the vein) for 24 hours.

Researchers took samples of blood, urine, and feces from participants during the study and measured the amount of radiolabelled PF-07304814. Researchers also checked the participants' health during the study and asked them how they were feeling. The details of how the study was done are shown in Figure 1.

Figure 1. **How was the Study done?**



Researchers then used the information to find out how PF-07304814 entered and moved through the body and how long it stayed in the body.

Where did this study take place?

The Sponsor ran this study at one location in the United States.

When did this study take place?

The study began on 07 October 2021 and ended 10 December 2021.

Who participated in this study?

The study included healthy male participants only who were willing to comply with all tests and procedures that were needed to be done in the study and had a healthy body weight. If the participants had any medical conditions or infections, they were not eligible to participate.

- All participants were between the ages of 18 and 45 years

All participants who started the study, finished the study.

How long did the study last?

The entire study took approximately 2 months to complete.

When the study ended in December 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?

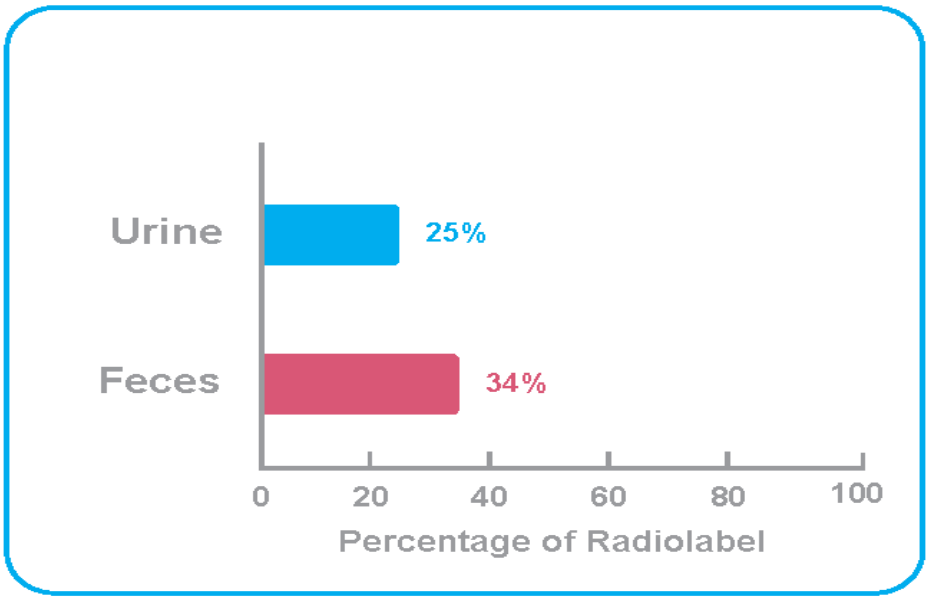
During the study, how much radiolabelled PF-07304814 was found in the urine and feces of participants?

Only small amounts of PF-07304814 were found in the blood, urine, and feces of participants in this study. Most of PF-07304814 was broken down by the body to form smaller molecules.

What was the amount of radiolabel excreted in the urine and feces of participants after they took 500 mg of radiolabelled PF-07304814?

The average amount of radiolabel excreted in the urine and feces after participants took radiolabelled PF-07304814 is shown in Figure 2.

Figure 2. Amount of Radiolabel excreted in Urine and Feces



- The highest amount of PF-07304814 in the blood during the 24 hours after participants took 500 mg of PF-07304814 was 360 nanogram per milliliter, also called ng/mL.

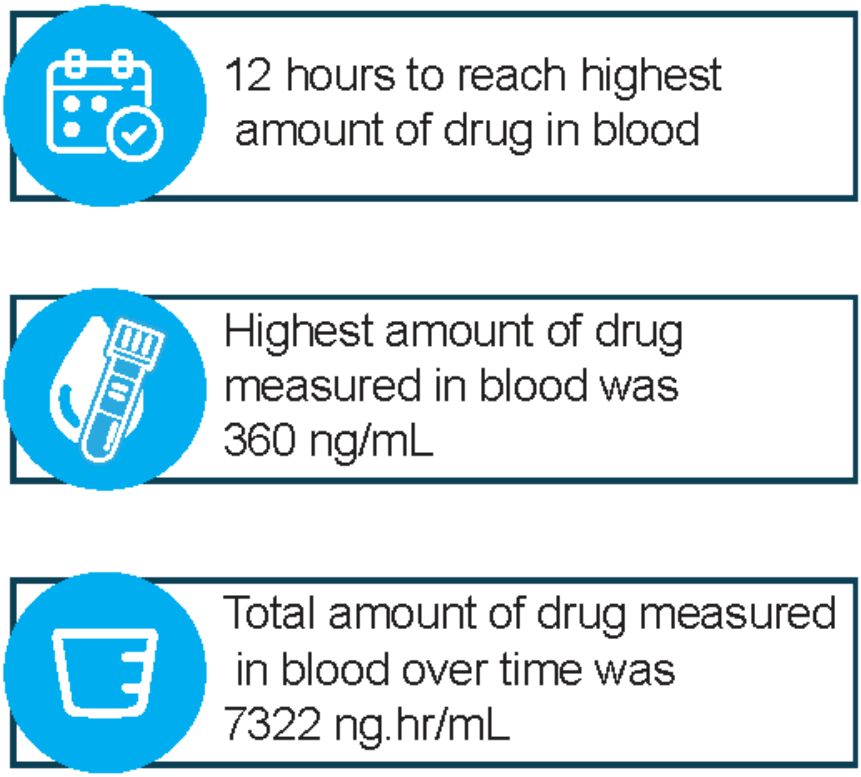
How long did it take for PF-07304814 to reach its highest amount in the blood after participants took 500 mg of PF-07304814?

It took 12 hours for PF-07304814 to reach its highest amount in the blood after participants took 500 mg of PF-07304814.

What was the total amount of PF-07304814 from when PF-07304814 was taken to the time when lowest amount was detected in the blood?

The total amount of PF-07304814 from when PF-07304814 was taken to the time when lowest amount was detected in the blood was 7322 ng.hr/mL.

Figure 3. Amount of Total PF-07304814



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.

3 out of 5 (60%) participants in this study had at least 1 medical problem. No participants left the study because of medical problems. All medical problems reported are described below.

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 are reported.
- The **2nd** column tells how many of the 5 participants taking the study medication reported each medical problem. Next to this number is the percentage of the 5 participants taking the study medication who reported the medical problem.
- Using these instructions, you can see that 1 out of the 5 (20%) participants taking the study medication reported constipation.

Table 1. Medical problems reported by study participants	
Medical Problem	**Study Medication (5 Participants)**
Constipation	1 out of 5 participants (20%)
Loose Motions	2 out of 5 participants (40%)
Reddening of Skin	1 out of 5 participants (20%)

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 had any 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 **NCT05050682**

www.pfizer.com/research/research_clinical_trials/trial_results — Use the protocol number C4611003

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!