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: Ervogastat (PF-06865571)

Protocol Number: C2541007

Dates of Study: 11 May 2021 to 06 August 2021

Title of this Study: A Study in Healthy Adult Male Participants to Assess Absorption, Distribution, Metabolism and Excretion (ADME) of Radiolabeled PF-06865571

[A Phase 1, Open-Label, Fixed-Sequence, 2-Period Study in Healthy Adult Male Participants to Assess the Extent of Excretion, Absolute Bioavailability, Fraction Absorbed, and Pharmacokinetics of [^{14}C]PF-06865571 Using a ^{14}C-Microtracer Approach]

Date(s) of this Report: 08 August 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 Non-Alcoholic Steatohepatitis with Liver Fibrosis?

Non-Alcoholic Steatohepatitis (NASH) with liver fibrosis is a medical condition where there is a high amount of fat in the liver along with inflammation (swelling) and fibrosis (scarring) that causes a stiff liver.

What is ervogastat?

Ervogastat (PF-06865571) is a new investigational drug that is taken by mouth that has not yet been approved for use by health authorities. Ervogastat blocks a specific enzyme (protein) called "DGAT2" and prevents the body from making certain types of fats. Too much fat in the liver is the first step toward development of NASH and liver scarring. Ervogastat decreases the storage of fat in the liver, which may help treat NASH with liver scarring.

What was the purpose of this study?

The purpose of this study was to find out how much ervogastat was in the participants' blood, urine, and feces after they took a "radio-labeled" form of ervogastat. A radiolabel is a radioactive particle attached to a drug that lets scientists measure the amount of study drug in the body. Researchers also wanted to see how ervogastat is broken down or changed by the body. This was done by measuring the amount of drug "metabolites" of ervogastat. Metabolites are the chemicals formed as a drug is broken down by the body.

When ervogastat was injected or swallowed, ervogastat entered the body and moved through the body. Ervogastat entered the blood and organs (for example, stomach, liver, and kidneys) when it moved through the body. Afterwards, ervogastat was removed from the body through urine and feces.

Researchers wanted to know:

- **How much radiolabeled ervogastat was found in the urine and feces of participants during the study?**
- **How was ervogastat metabolized (changed or broken down) by the participants' bodies?**

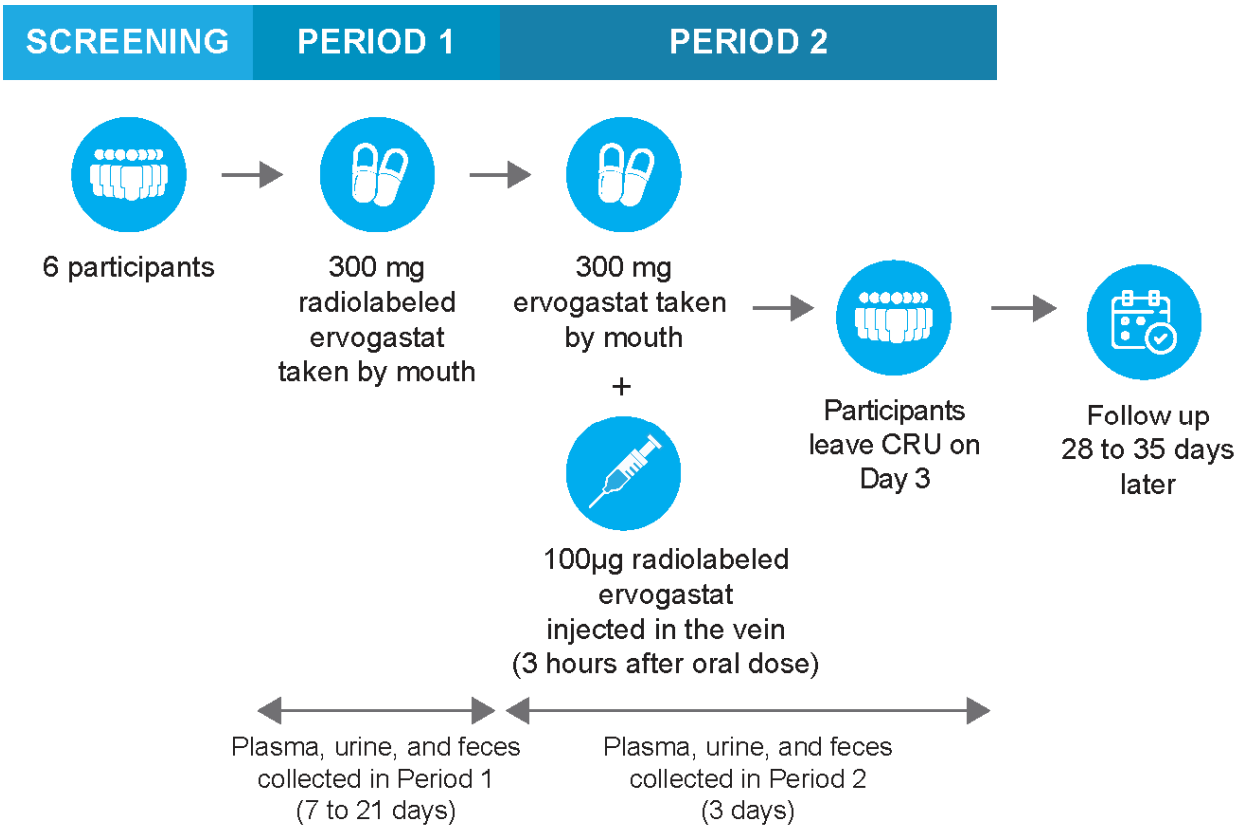
What happened during the study?

How was the study done?

Researchers tested 2 different regimens on a group of healthy male participants to learn how ervogastat was handled by the body:

- At the beginning of the first period (Regimen A), participants took one 300 mg dose of radiolabeled ervogastat by mouth.
- At the beginning of the second period (Regimen B), participants first took one 300 mg dose of unlabeled ervogastat by mouth. After 3 hours, the participants then received one 100 microgram (µg) dose of radiolabeled ervogastat by injection into a vein or intravenously (IV).

Researchers took samples of blood, urine, and feces from participants during the study and measured the amount of ervogastat and its metabolites. Researchers also checked the participants' health during the study and asked them how they were feeling. A diagram of the study design is shown on the next page.



This study was an "open-label" study. An open-label study means that the participants and researchers knew what was being given to each participant during the study.

Where did this study take place?

The Sponsor ran this study at 1 site in the United States of America.

When did this study take place?

It began on 11 May 2021 and ended on 06 August 2021.

Who participated in this study?

The study included healthy male participants who met the inclusion/exclusion criteria for things such as age, body weight, and body mass index (BMI).

- A total of 6 men participated

- No women participated
- All participants were between the ages of 25 and 61 years

Of the 6 participants who started the study, all 6 finished the study. No participants left before the study was over by their choice or a doctor decided it was best for a participant to stop being in the study.

How long did the study last?

Study participants were in the study for around 8 weeks. The entire study took around 3 months to complete.

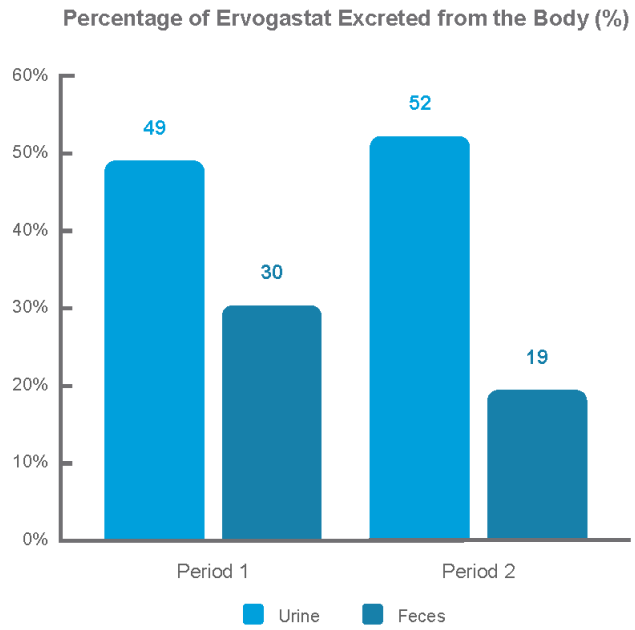
When the study ended in August 2021, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

How did radiolabeled ervogastat act in the body?

How much radiolabeled ervogastat was found in the urine and feces of participants during the study?

- In Period 1, an average of 79% of the radiolabeled drug taken by mouth was found in the participants' urine and feces. Most of the drug was eliminated from the participants' bodies in the first 4 days after taking the drug by mouth.



- In Period 2, an average of 70% of the radiolabeled drug given by IV was found in the participants' urine and feces. This occurred in the 2 days after being given the drug by IV.

How was ervogastat metabolized (changed or broken down) by the participants' bodies?

- The study found that there were 2 most common metabolites of ervogastat (called "M2" and "M6"). "M2" accounted for 37% and "M6" accounted for 11% of the radioactivity in the participants' blood plasma.

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 underlying disease or by chance). Or, medical problems could also have been caused by the study drug 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.

During Period 1, 4 out of the 6 (67%) participants in this study had at least 1 medical problem. No medical problems occurred during Period 2. No participants left the study because of medical problems. The medical problems reported by the participants are described below.

Instructions for Understanding Table 1.

- The 1st column of Table 1 lists medical problems that were reported during the study. All medical problems reported by the participants are listed.
- The 2nd column tells how many of the participants taking the study medication reported each medical problem in Period 1. Next to this number is the percentage of the participants taking the study medication who reported the medical problem.
- The 3rd column tells how many of the participants reported each medical problem in Period 2.
- Using these instructions, you can see that 2 out of the 6 (33%) participants taking the study medication reported diarrhea in Period 1. A total of 0 out of the 6 (0%) participants in Period 2 reported diarrhea.

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 serious medical problems and no participants died in this study.

Table 1. Medical problems reported by study participants

Medical Problem	Period 1 300 mg ervogastat by mouth (6 Participants)	Period 2 300 mg ervogastat by mouth + 100 µg IV (6 Participants)
Diarrhea	2 out of 6 participants (33%)	0 out of 6 participants (0%)
Red, itchy eyes due to an allergy	1 out of 6 participants (17%)	0 out of 6 participants (0%)
Urine abnormality	1 out of 6 participants (17%)	0 out of 6 participants (0%)
Itchy throat	1 out of 6 participants (17%)	0 out of 6 participants (0%)
Postnasal drip causing persistent cough	1 out of 6 participants (17%)	0 out of 6 participants (0%)
Skin irritation	1 out of 6 participants (17%)	0 out of 6 participants (0%)
Itchy skin	1 out of 6 participants (17%)	0 out of 6 participants (0%)
Flushed (red) skin	1 out of 6 participants (17%)	0 out of 6 participants (0%)

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.

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

www.clinicaltrials.gov
www.pfizer.com/research/research_clinical_trials/trial_results

Use the study identifier **NCT04866225**
Use the protocol number C2541007

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!