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: Atirmociclib (PF-07220060)

Protocol Number: C4391010

Dates of Study: 31 January 2024 to 12 April 2024

Title of this Study: A Study to Understand What the Body Does to the Study Medicine Called Atirmociclib When Taken by Healthy Men

[A Phase 1, Open-Label, Parallel-Group, Single-Dose Study in Healthy Adult Male Participants to Investigate the Absorption, Distribution, Metabolism and Excretion of [14C]-PF-07220060 and to Assess the Absolute Bioavailability and Fraction Absorbed of PF-07220060 Using a 14C-Microtracer Approach]

Date of this Report: 08 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.

Why was this study done?

What are solid tumors?

Cancer is a disease in which abnormal cells divide and multiply out of control, eventually forming a growth also known as tumor. Solid tumors are the most common type of cancer, making up about 80% to 90% of all cases. This includes, for example, cancer that forms in the skin, breast, colon, lungs, bone and connective tissue.

What is Atirmociclib?

Atirmociclib is a new medicine, under development, that may be used for the treatment of cancer. Atirmociclib inhibits the activity of a protein called Cyclin-dependent kinase 4 (CDK4). This protein plays a role in how fast cells divide and grow. When certain components (proteins) of the cell are irregulated, CDK4 can be overactivated and lead to the formation of certain types of cancer. By inhibiting CDK4, researchers hope that atirmociclib can inhibit tumor growth. There are already approved drugs in the market that inhibit CDK4, which also inhibits a similar protein called Cyclin-dependent kinase 6 (CDK6). Inhibiting CDK6 can lead to problems with the production of cells circulating in the blood. Atirmociclib is designed to inhibit CDK4 far more than CDK6.

For this study, atirmociclib was radioactively labelled with carbon-14 (14C). A radioactively labelled drug has a small amount of safe radioactive material attached to it. Tracking the release of activity from a radiolabelled drug helps researchers to understand how a drug moves through the body. The radioactive atirmociclib is referred as [14C] atirmociclib in this document.

What was the purpose of this study?

The purpose of this study was to learn how quickly and to what extent the study medicine atirmociclib was broken down in the body and removed from the body through urine and stool after giving a single oral dose.

This study did not test if the study medicine helps to treat cancer.

Researchers wanted to know:

- **What percent of [14C] atirmociclib dose was found in the urine and stool after taking a single oral dose?**
- **After the break down of atirmociclib in the body, what was the amount of [14C] atirmociclib and its breakdown product in blood, urine, and stool after taking a single oral dose?**

What happened during the study?

How was the study done?

Researchers tested a single dose of atirmociclib on a group of healthy participants to learn how atirmociclib is processed and transformed in the body.

This study consisted of 3 periods, as follows:

Screening period (up to 28 days before study start): During the screening period, researchers examined the healthy participants and identified those who could take part in the study.

Treatment period (15 days): During the treatment period, the participants took study medicine and researchers learned about the levels of atirmociclib in participants' blood, urine, and stool samples.

This study consisted of two groups as shown in Figure 1:

In Group 1, 6 participants took a single dose of [14C] atirmociclib by mouth. In this group, the participants stayed at the clinic site for up to 15 days.

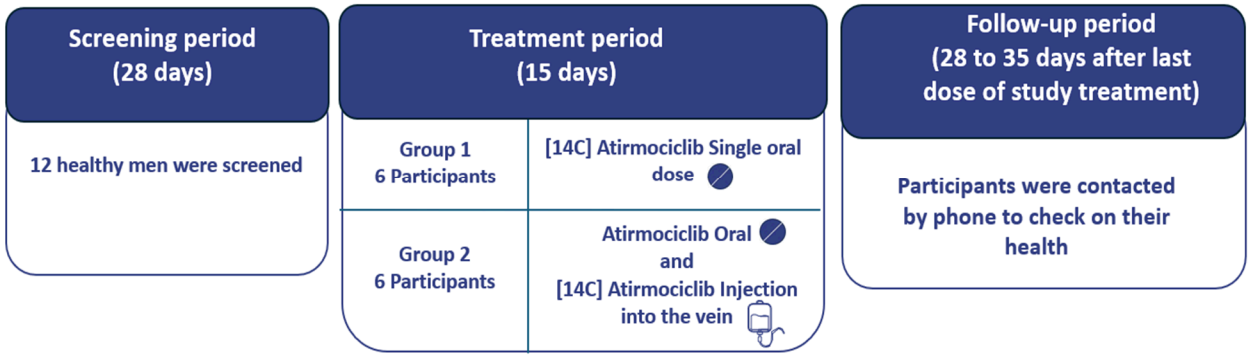
In Group 2, 6 participants took single dose of unlabeled atirmociclib by mouth. Further they received a very small dose of [14C] atirmociclib as an injection into a vein also known as “intravenous” (IV) at the study clinic. The injection was given 2 hours after the oral administration. In this group, the duration of participants' stay depended on the results of Group 1.

Study medicine was given after an overnight fast of at least 10 hours in both the groups. In this study both the healthcare provider and the participant knew the medicine being given. This is called “open-label”.

Researchers took samples of blood, urine, and stool from participants during the study to measure the level of atirmociclib. Researchers also checked the participants’ health during the study and asked them how they were feeling.

Follow-up period (28 to 35 days after last dose of study treatment): At the end of the study, participants were contacted by phone to check on their health.

Figure 1: What Happened During the Study



Where did this study take place?

The Sponsor ran this study in the Netherlands.

When did this study take place?

It began 31 January 2024 and ended 12 April 2024.

Who participated in this study?

The study included healthy male participants with a body mass index (a measure of body weight in relation to height) of 17.5 to 30.5 kilograms per square meter (kg/m^2) and weighing more than 50 kg.

- A total of 12 men in participated.
- All participants were between the ages of 23 years and 64 years.

All the 12 participants finished the study.

How long did the study last?

Study participants were in the study for around 2 months. The entire study took about 2 and a half months to complete.

When the study ended in April 2024, 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?

What percent of [14C] atirmociclib dose was found in the urine and stool after taking a single oral dose?

To answer this question, the researchers took urine and stool samples from the participants before and after they took the single oral dose of study medicine.

In this study, when participants took [14C] atirmociclib, 12% of it was found in their urine and 75% was found in their stools.

After the break down of atirmociclib in the body, what was the amount of [14C] atirmociclib and its breakdown product in blood, urine, and stool after taking a single oral dose?

To answer this question, the researchers took blood, urine and stool samples from the participants before and after they took the single oral dose of the study medicine.

The study medicine breaks down into smaller products some of which may show medicine activity. These are called breakdown products.

After taking the medicine atirmociclib, most of it in the blood was still in its original form, making up about 69% of what was measured. A part of the medicine broke down into something called M5, which we found in the blood, making up 32% of what was measured.

Understanding these changes is important because it shows us how the medicine acts in the body and helps us know if it's safe and effective.

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.

In both the groups, 4 out of 6 participants (67%) in this study had at least 1 medical problem. No participant left the study because of medical problems. All medical problems – those are reported by participants – are described below in Table 1.

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 by at least 1 participant are listed.
- The **2nd** column tells how many of the 6 participants who took the study medicine in Group 1 reported each medical problem. Next to this number is the percentage of the 6 participants who took the study medicine in Group 1 and reported the medical problem.
- The **3rd** column tells how many of the 6 participants who took the study medicine in Group 2 reported each medical problem. Next to this number is the percentage of the 6 participants who took study medicine in Group 2 and reported the medical problem.
- Using these instructions, you can see that 1 out of the 6 participants (17%) in Group 1 and no participant in Group 2 reported blocked nose.

Table 1. Commonly reported medical problems by study participants		
Medical Problem	**(Group 1) [14C] Atirmociclib oral (6 Participants)**	**(Group 2) Atirmociclib oral + [14C] Atirmociclib IV (6 Participants)**
A blocked nose	1 out of 6 participants (17%)	0 out of 6 participants
Cough	0 out of 6 participants	1 out of 6 participants (17%)
Dry skin	1 out of 6 participants (17%)	0 out of 6 participants
Pain in the arms or legs	0 out of 6 participants	1 out of 6 participants (17%)
Flu like illness	1 out of 6 participants (17%)	0 out of 6 participants
Headache	1 out of 6 participants (17%)	2 out of 6 participants (33%)
Indigestion	1 out of 6 participants (17%)	0 out of 6 participants
Irritation at the site of the application (like at the injection site)	0 out of 6 participants	1 out of 6 participants (17%)
Pain in mouth and throat	1 out of 6 participants (17%)	0 out of 6 participants

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Table 1. Commonly reported medical problems by study participants		
Medical Problem	**(Group 1) [14C] Atirmociclib oral (6 Participants)**	**(Group 2) Atirmociclib oral + [14C] Atirmociclib IV (6 Participants)**
Skin irritation	0 out of 6 participants	1 out of 6 participants (17%)
Stomach pain	0 out of 6 participants	1 out of 6 participants (17%)

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.

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 **C4391010**

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

www.clinicaltrials.gov

Use the study identifier **NCT06267963**

https://euclinicaltrials.eu

Use the study identifier **2023-507074-40-00**

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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