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:	Ritlecitinib (PF-06651600)
Protocol Number:	B7981086
Dates of Study:	01 February 2024 to 28 March 2024
Title of this Study:	A Study to Learn About Three Forms of The Study Medicine (Ritlecitinib) in Healthy Adults [A Phase 1, Open-Label Study in Healthy Participants to Investigate the Pharmacokinetics of Ritlecitinib Following Single Oral Administration of Modified Release Formulations Under Fed and Fasted Conditions]
Date(s) of this Report:	21 January 2025

– 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 an autoimmune disease?

An autoimmune disease is a condition where a person's immune system mistakenly attacks healthy parts of their body.

Autoimmune diseases can damage the gut (ulcerative colitis, Crohn's disease), hair roots (alopecia areata), joints (rheumatoid arthritis), and skin color (vitiligo).

What is ritlecitinib?

Ritlecitinib (ri-tul-SIT-in-ib) (LITFULO™) is a medicine that is approved for the treatment of people 12 years of age and older with severe alopecia areata. Ritlecitinib was used in forms that were investigational treatments in this study. This means that it was not approved for use outside of research studies in these forms.

Ritlecitinib is a small molecule medication that is taken by mouth. Small molecules can move into cells and interact with other molecules present inside a cell. Ritlecitinib is thought to work by blocking the activity of specific proteins in immune cells called "Janus Kinase 3" and the "TEC family kinases". These proteins act like on/off switches for the cells of the immune system. By turning off these switches, the cells of the immune system produce fewer cytokines. Cytokines are a type of protein that activate the immune system. Producing fewer cytokines is expected to improve the symptoms of some autoimmune diseases.

What is a modified-release medicine?

A modified-release medicine is given in a form that changes how much time the medicine takes to get into the body. There were 2 new modified-release forms of ritlecitinib being tested in this study, called MR1 and MR2.

What was the purpose of this study?

The purpose of this study was to see what effect taking 3 different forms of ritlecitinib had on the levels of ritlecitinib in the blood. The 3 forms were the 2 new modified-release forms MR1 and MR2, and 1 standard liquid form. The main purpose of this study was to look at this effect when participants took ritlecitinib on an empty stomach with no food. This is called a "fasted" condition.

This study did not test if ritlecitinib could help to treat any autoimmune conditions.

Researchers wanted to know:

- **What was the level of ritlecitinib in the blood when it was taken as modified-release capsules compared to the standard liquid form, under fasted conditions?**

What happened during the study?

How was the study done?

First, researchers checked each participant to make sure they were able to join the study. This is known as screening.

Participants were then enrolled to stay at the study center for 13 days and 12 nights. Participants were to arrive at the study center the day before their 1st treatment. During their stay, participants were given the following treatments:

Treatment A → **Ritlecitinib 100 mg** as liquid, by mouth

Treatment B → **Ritlecitinib 100 mg** as 2 MR1 capsules, by mouth

Treatment C → **Ritlecitinib 100 mg** as 2 MR2 capsules, by mouth

Participants were to be treated 4 times. All participants were to be given Treatments A, B, and C in a fasted condition. After this, half the participants were given Treatment B in a fed condition. The other half of the participants were given Treatment C in a fed condition. A fed condition means they took the treatment with a high-fat meal. Participants were assigned to receive their treatments in different orders (sequences). There were 6 different treatment sequences, with 2 participants in each sequence.

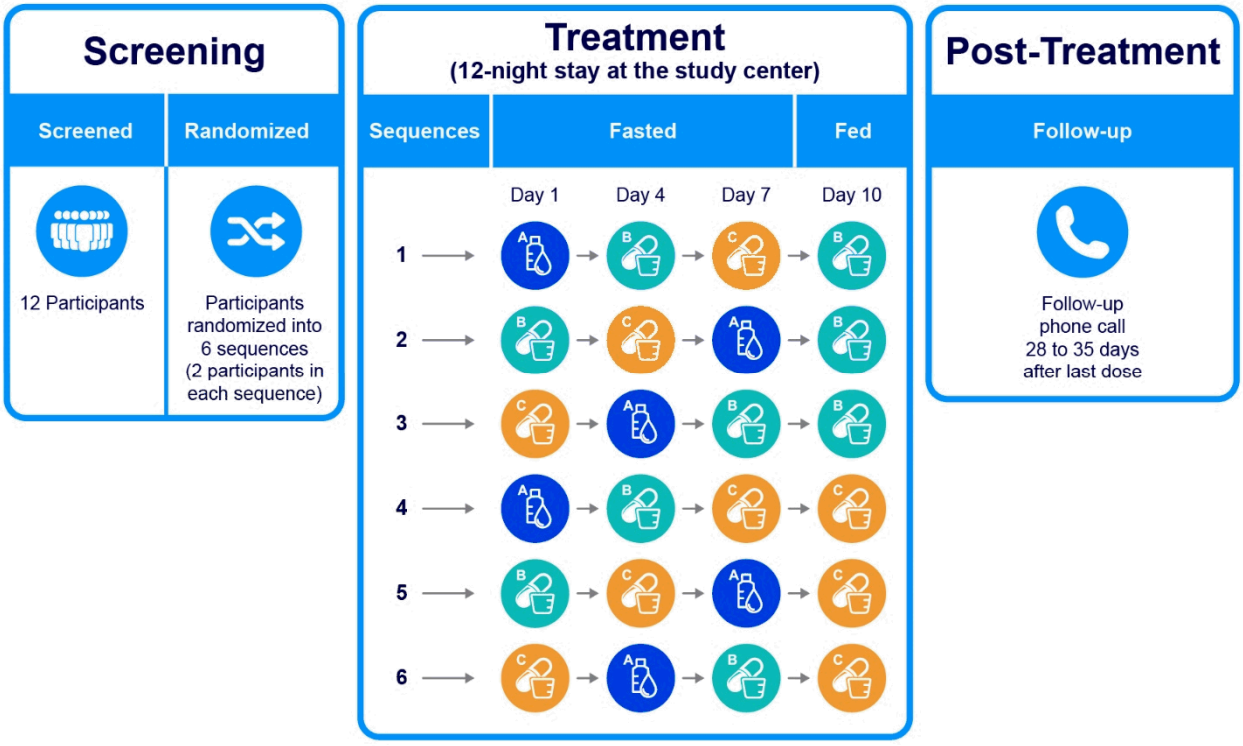
Researchers took samples of blood from participants during the study and measured the amount of ritlecitinib in the blood. Researchers checked the participants' health during the study and asked them how they were feeling. Participants also received a telephone call between 28 and 35 days after their last dose of study treatment, to check on their health.

The participants and researchers knew who took the different treatments during the study. This is known as an "open-label" study.

Participants were assigned to each treatment sequence by chance alone. This is known as a “randomized” study.

A diagram showing what happened in this study is provided in Figure 1.

Figure 1. Study plan



Where did this study take place?

The Sponsor ran this study at 1 location in Belgium.

When did this study take place?

It began 01 February 2024 and ended 28 March 2024.

Who participated in this study?

The study included healthy adult participants.

- A total of 11 men participated.
- A total of 1 woman participated.
- All participants were between the ages of 22 and 70 years.

Of the 12 participants who started the study, 11 completed the study. One (1) participant left before the study was over due to a medical problem. They did not take their last 2 treatments. Medical problems are described in another section of this report.

How long did the study last?

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

When the study ended in March 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?

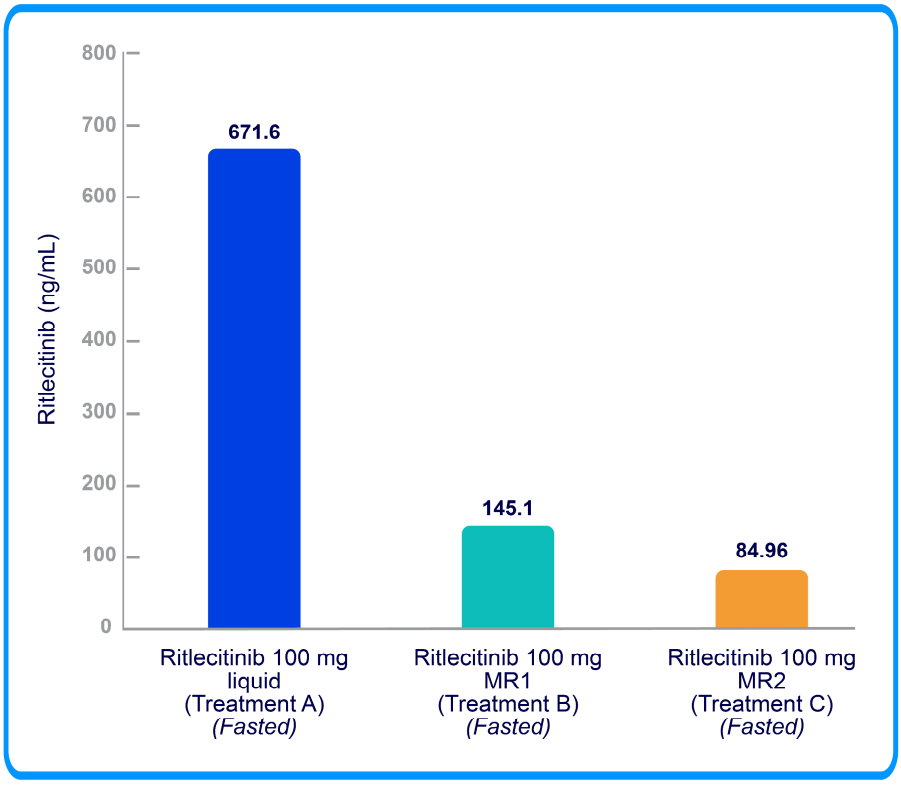
What was the level of ritlecitinib in the blood when it was taken as modified-release capsules compared to the standard liquid form, under fasted conditions?

To answer this question, researchers compared the average levels of ritlecitinib in participants' blood after they took each treatment.

What was the amount of ritlecitinib in the blood after each treatment?

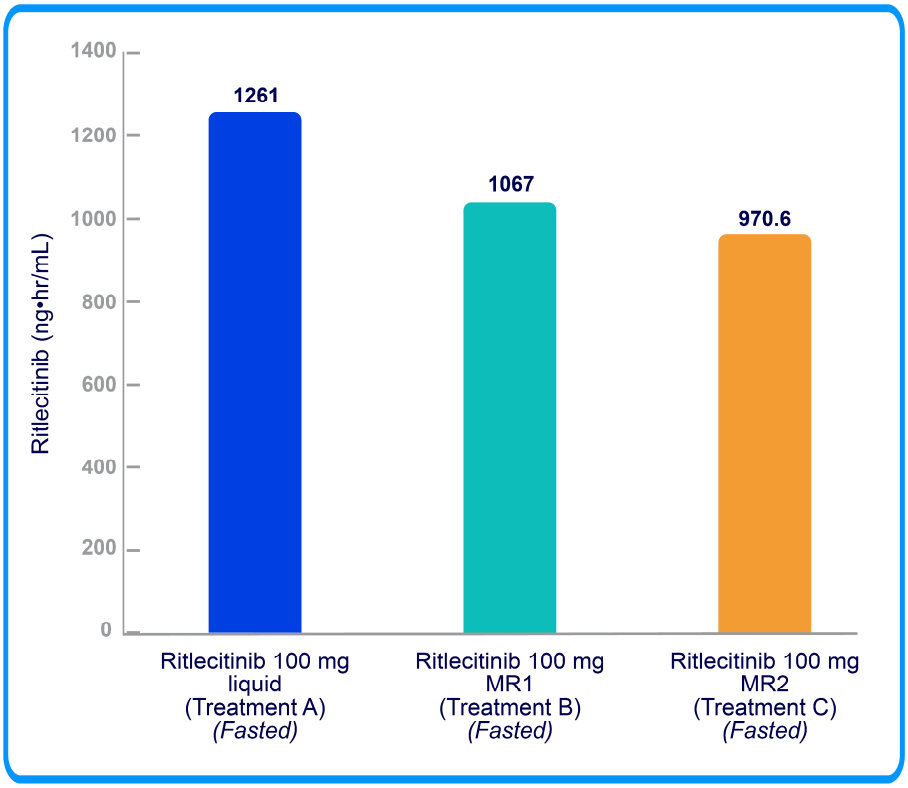
- The highest amount of ritlecitinib in the blood after participants took each treatment is shown in Figure 2. The amount of drug in the blood was measured in nanograms per milliliter, also called ng/mL.

Figure 2. Highest amount of ritlecitinib in the blood (fasted)



- The estimated total amount of ritlecitinib in the blood from when ritlecitinib was taken until ritlecitinib was removed from the body is shown in Figure 3 for each treatment. This was measured in nanogram hours per milliliter, also called ng•hr/mL. The ng•hr/mL is a unit used to measure the total amount of drug over time in the blood.

Figure 3. Estimated total amount of ritlecitinib in the blood (fasted)



Based on all these results, the researchers decided that:

- The highest level of ritlecitinib in the blood was lower when fasted participants took the modified-release forms than when they took the standard liquid form.
- Fasted participants had a lower amount of ritlecitinib in their blood when they took the modified-release forms than when they took the standard liquid form.

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.

In this study, the total numbers of participants who had at least 1 medical problem were:

- Three (3) out of 12 participants (25.0%) taking Treatment A (fasted).
- Five (5) out of 11 participants (45.5%) taking Treatment B (fasted).
- Three (3) out of 12 participants (25.0%) taking Treatment C (fasted).
- Zero (0) out of 5 participants taking Treatment B (fed).
- One (1) out of 6 participants (16.7%) taking Treatment C (fed).

A total of 1 participant left the study because of a medical problem. The medical problem was a type of heart rhythm disorder called “first-degree atrioventricular block”. It happened when the participant was taking Treatment A. The researchers did not believe that this medical problem was related to the study treatment.

The most common medical problem – defined as a problem reported more than once – was bruising under the skin. This was reported by:

- Zero (0) out of 12 participants taking Treatment A (fasted).
- One (1) out of 11 participants (9.1%) taking Treatment B (fasted).
- Three (3) out of 12 participants (25.0%) taking Treatment C (fasted).
- Zero (0) out of 5 participants taking Treatment B (fed).
- Zero (0) out of 6 participants taking Treatment C (fed).

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. 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 **B7981086**

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

www.clinicaltrials.gov	Use the study identifier **NCT06172348**
https://euclinicaltrials.eu	Use the study identifier **2023-505603-23-00**

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!