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:	Ritlecitinib (PF-06651600)
Protocol Number:	B7981030
Dates of Study:	10 September 2021 to 19 November 2021
Title of this Study:	A Single Dose Study to Test Two Pediatric Forms of Ritlecitinib Compared With Adult Ritlecitinib in Healthy Adults) [A Phase 1, Randomized, Open-Label, Cross-Over, Single Dose Study to Estimate the Relative Bioavailability of Pediatric Ritlecitinib (PF-06651600) Capsules and Spray Congealed Beads Relative to Adult Capsules in Healthy Adult Participants]
Date(s) of this Report:	24 May 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 are "autoimmune diseases"?

Diseases such as alopecia areata (bald patches), rheumatoid arthritis (swelling and pain in the joints and surrounding tissues), vitiligo (loss of skin pigment), ulcerative colitis (inflammation and ulcers in the large intestine), and Crohn's disease (inflammatory bowel disease) are often called "autoimmune diseases". This means that patients with one or more of these conditions have an immune system that mistakenly attacks healthy parts of the body. Under normal circumstances, the immune system helps your body recognize and defend itself against bacteria, viruses, and substances that may be harmful. Treatments for autoimmune diseases focus on changing the activity of the immune system. However, these treatments do not work for all patients, may cause their own health problems, or may only be able to be used for a brief period of time, depending on the treatment. Researchers are looking for new treatments for autoimmune diseases that work well for the disease, cause fewer health problems, and can be taken for longer periods of time.

What is Ritlecitinib?

Ritlecitinib is an investigational drug that is being studied to treat people with inflammatory conditions and diseases. An investigational treatment is one that is still being studied and is not approved for use outside of research studies. Ritlecitinib is a small molecule oral medication. Small molecules can move easily through the cell membrane and interact with 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 are expected to produce fewer cytokines (a type of protein), which is expected to make autoimmune diseases better.

What was the purpose of this study?

The purpose of this study was to measure and compare how much ritlecitinib was in the participants' blood when given as pediatric capsules (Treatment B - three 10 mg capsules which are smaller than the normal adult capsules) or 30 mg spray congealed beads (Treatment C), when compared to a single 30 mg adult capsule (Treatment A). After ritlecitinib was swallowed, ritlecitinib entered the body and moved through the body. Ritlecitinib entered the blood and organs (for example, stomach, liver, and kidneys) when it moved through the body. Afterwards, ritlecitinib was removed from the body through urine and feces.

This study did not test if the drug helps to improve inflammatory conditions and diseases and only focused on how ritlecitinib moves through the body.

Researchers wanted to know:

- **How did three 10 mg capsules, 30 mg spray congealed beads, or a single 30 mg capsule of ritlecitinib behave in the body?**
- **What medical problems did participants have during the study?**

What happened during the study?

How was the study done?

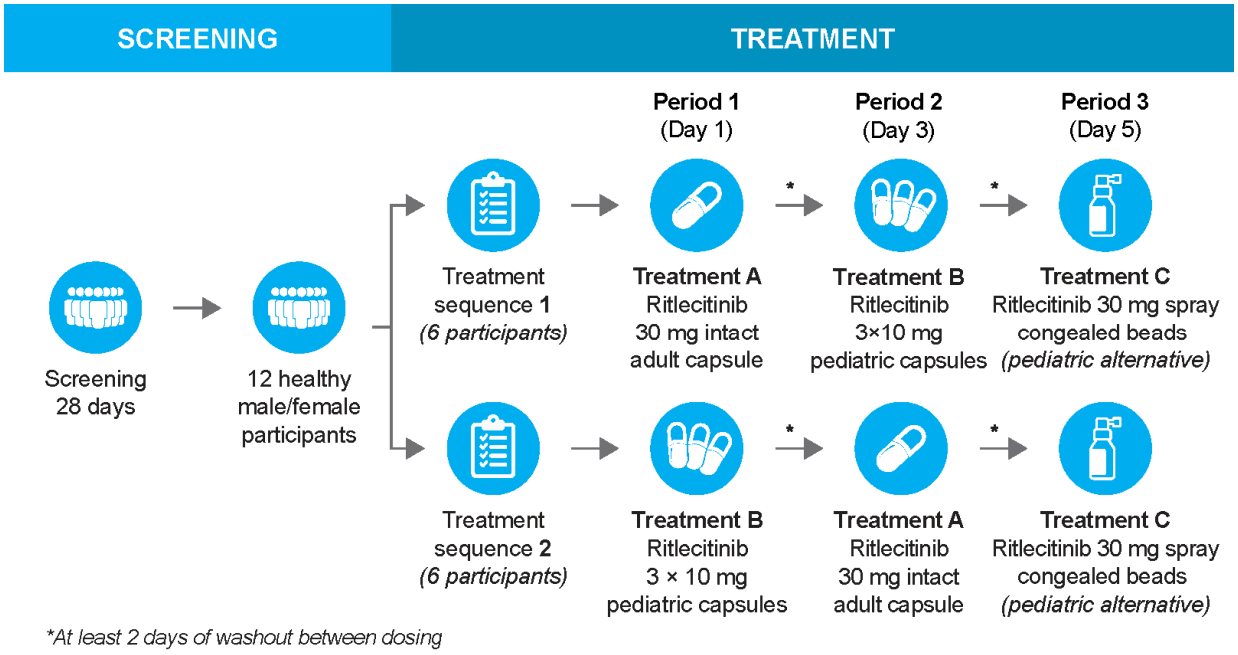
Researchers tested three 10 mg capsules or 30 mg spray congealed beads of ritlecitinib relative to a single 30 mg capsule of ritlecitinib on a group of healthy participants to learn how ritlecitinib behaved in the body.

This study included 3 treatment periods with at least 2 days of 'washout' between any two (2) consecutive periods (no treatment given to participants on those days to allow time for a drug to be removed from the body). Participants were randomized into

2 sequences of treatment. Participants were assigned to each sequence by chance alone.

- **Period 1 (Day 1):**
    - 6 participants took a single 30 mg capsule of ritlecitinib orally (by mouth) (Treatment A)
    - 6 participants took three 10 mg capsules of ritlecitinib orally (by mouth) (Treatment B)
- **Period 2 (Day 3):**
    - Participants who took a single 30 mg capsule of ritlecitinib in Period 1 took three 10 mg capsules of ritlecitinib in Period 2
    - Participants who took three 10 mg capsules of ritlecitinib in Period 1 took a single 30 mg capsule of ritlecitinib in Period 2
- **Period 3 (Day 5):**
    - All participants took 30 mg spray congealed beads of ritlecitinib orally (by mouth) (Treatment C)

This was an open-label study, which means that the participants and the researchers knew which treatments the participants received. The study design is shown on the next page.



Researchers took samples of blood from participants during the treatment phase and measured the amount of ritlecitinib that was in their blood. Researchers then compared the blood samples from Period 1, Period 2, and Period 3. Researchers also checked the participants' health during the study and asked them how they were feeling.

Where did this study take place?

The Sponsor ran this study at 1 location in the United States.

When did this study take place?

It began on 10 September 2021 and ended on 19 November 2021.

Who participated in this study?

The study included healthy participants who met the inclusion criteria for things such as age, weight, and pregnancy status.

- A total of 10 men participated

- A total of 2 women participated
- All participants were between the ages of 23 and 56 years

Of the 12 participants who started the study, all 12 (100%) finished it.

How long did the study last?

Study participants were in the study for about 42 days. The entire study took about 2 months to complete and was completed as planned.

When the study ended in November 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?

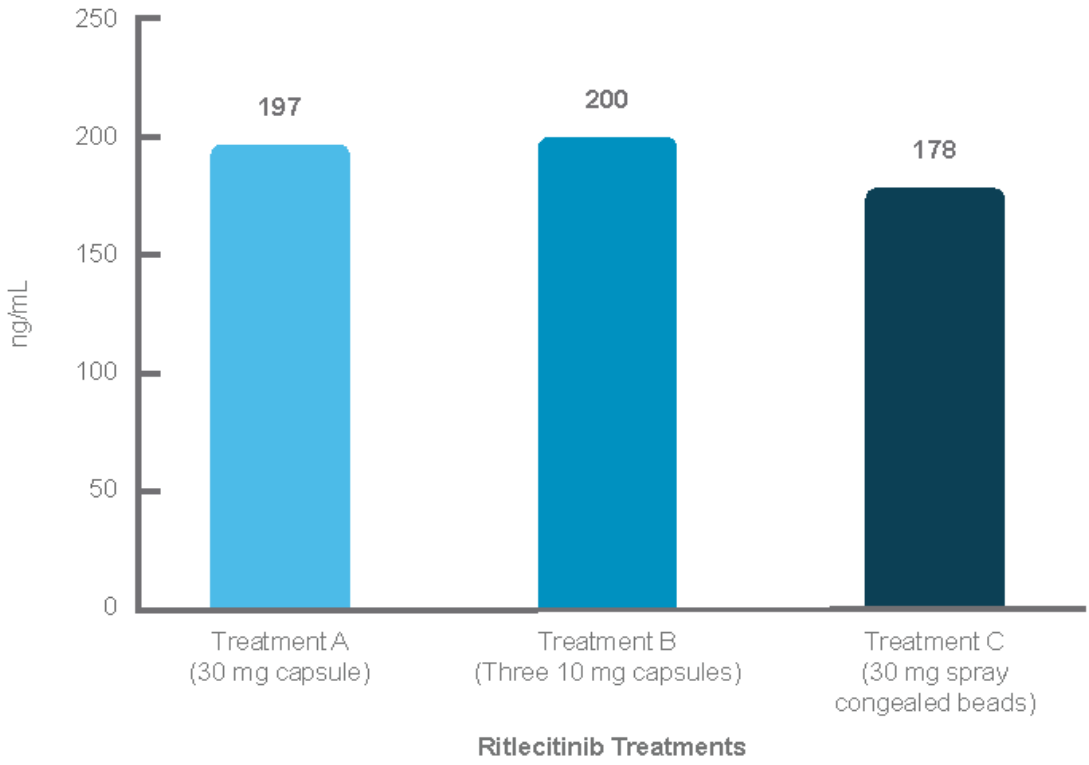
How did three 10 mg capsules of ritlecitinib, 30 mg spray congealed beads of ritlecitinib, or a single 30 mg capsule of ritlecitinib behave in the body?

To answer this question, the researchers compared the participants' blood samples from Period 1, Period 2, and Period 3.

What was the highest amount of ritlecitinib measured in the blood after participants took three 10 mg capsules, 30 mg spray congealed beads, or a single 30 mg capsule of ritlecitinib?

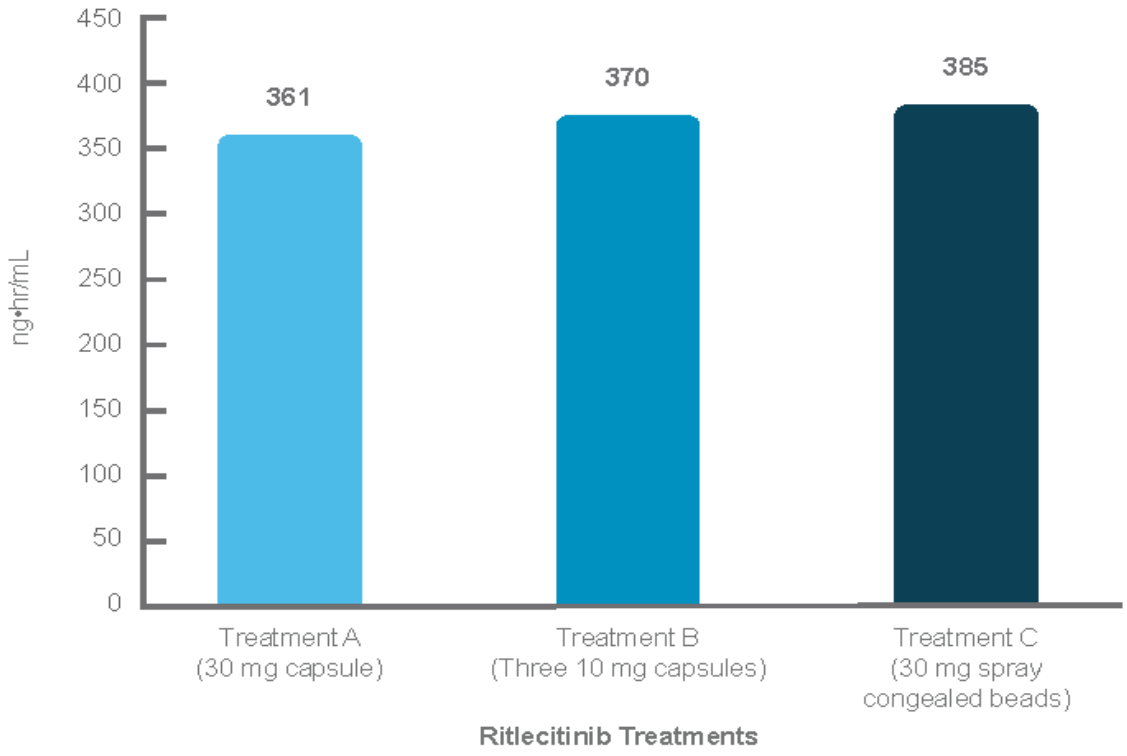
The highest amount of ritlecitinib measured in the blood after participants took three 10 mg capsules, 30 mg spray congealed beads, or a single 30 mg capsule of ritlecitinib is shown in Figure 1. The amount of drug in the blood was measured in nanograms per milliliter, also called ng/mL. In this study, the highest amount of ritlecitinib measured in the blood was similar between the 3 treatments. Researchers considered the differences in the results as minor.

Figure 1: Highest Amount of Ritlecitinib in the Blood



The estimated total amount of ritlecitinib in the blood from the time when ritlecitinib was taken until it was removed from the body is shown in Figure 2. The total amount of ritlecitinib in the blood was measured in nanogram hours per milliliter, also called ng•hr/mL. The results were similar across the 3 treatments.

Figure 2: Overall Amount of Ritlecitinib in the Blood



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 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.

Four (4) out of 12 participants (33%) in this study had at least 1 medical problem. None of the participants left the study because of medical problems. The medical problems reported by 1 or more participants 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 reported by 1 or more participants are listed.
- The **2nd to 4th** column tells how many of the 12 participants taking Treatment A, Treatment B, and Treatment C, respectively, reported each medical problem. Next to this number is the percentage of the 12 participants taking the study medication who reported the medical problem.
- Using these instructions, you can see that 2 out of the 12 participants (17%) taking study Treatment A reported pain at the site where a needle or catheter is inserted into a vein.

Table 1. Medical problems reported by study participants			
Medical Problem	Treatment A Ritlecitinib 1 x 30 mg Capsule (12 Participants)	Treatment B Ritlecitinib 3 x 10 mg Capsules (12 Participants)	Treatment C Ritlecitinib 30 mg Spray Congealed Beads (12 Participants)
Feeling tired	0 out of 12 participants (0%)	0 out of 12 participants (0%)	1 out of 12 participants (8%)
Pain at the site where a needle or catheter is inserted into a vein	2 out of 12 participants (17%)	0 out of 12 participants (0%)	0 out of 12 participants (0%)
Headache	0 out of 12 participants (0%)	1 out of 12 participants (8%)	0 out of 12 participants (0%)
Feeling sleepy or drowsy	0 out of 12 participants (0%)	1 out of 12 participants (8%)	0 out of 12 participants (0%)

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 in this study had serious medical problems, and 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.

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

www.clinicaltrials.gov	Use the study identifier **NCT05040295**
www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number B7981030

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!