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:	Temanogrel (APD791, PF-07915505)
Protocol Number:	APD791-204 (C5071001)
Dates of Study:	20 October 2021 to 02 September 2022
Title of this Study:	A Study to Assess the Effect of Oral Temanogrel on Digital Blood Flow in Adult Participants With Raynaud's Phenomenon Secondary to Systemic Sclerosis [A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled, Crossover Study to Assess the Effect of Oral Temanogrel on Digital Blood Flow in Subjects With Raynaud's Phenomenon Secondary to Systemic Sclerosis]
Date(s) of this Report:	23 April 2023

– 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 Raynaud's phenomenon?

Raynaud's phenomenon is a condition that involves decreased blood flow to the fingers and toes. People with Raynaud's phenomenon may experience numbness, pain, and color changes in their fingers and toes, particularly when they are cold or under emotional stress. Raynaud's phenomenon can occur along with other medical conditions, such as systemic sclerosis (a disease where the body's immune system attacks itself leading to tightening and hardening of the skin).

What is temanogrel?

Temanogrel is an investigational treatment that may reduce the symptoms of Raynaud's phenomenon. An investigational treatment is one that has not been approved for use outside of a research study. Temanogrel is given as a capsule taken by mouth.

What was the purpose of this study?

The main purposes of this study were to learn more about the safety and about the possible effectiveness of temanogrel in people with Raynaud's phenomenon and systemic sclerosis.

Researchers wanted to know:

Did temanogrel improve blood flow in the fingers?

What medical problems did participants have during the study?

What happened during the study?

How was the study done?

Researchers studied participants to learn more about the safety and the possible effectiveness of temanogrel in people with Raynaud's phenomenon and systemic sclerosis.

Participants included in the study:

- Were examined by a study doctor and determined to be appropriate to participate
- Were 18 to 75 years of age
- Had Raynaud's phenomenon and systemic sclerosis

First, a study doctor checked each potential participant to make sure they were appropriate to join the study. This is known as the screening period. This study was planned to include 2 stages, Stage A and Stage B.

Participants in Stage A were expected to attend 3 study visits, with a break of about 3 to 7 days between each visit (known as the "washout period"). They were randomized (assigned by chance) to receive 1 of 3 dosing options at each study visit:

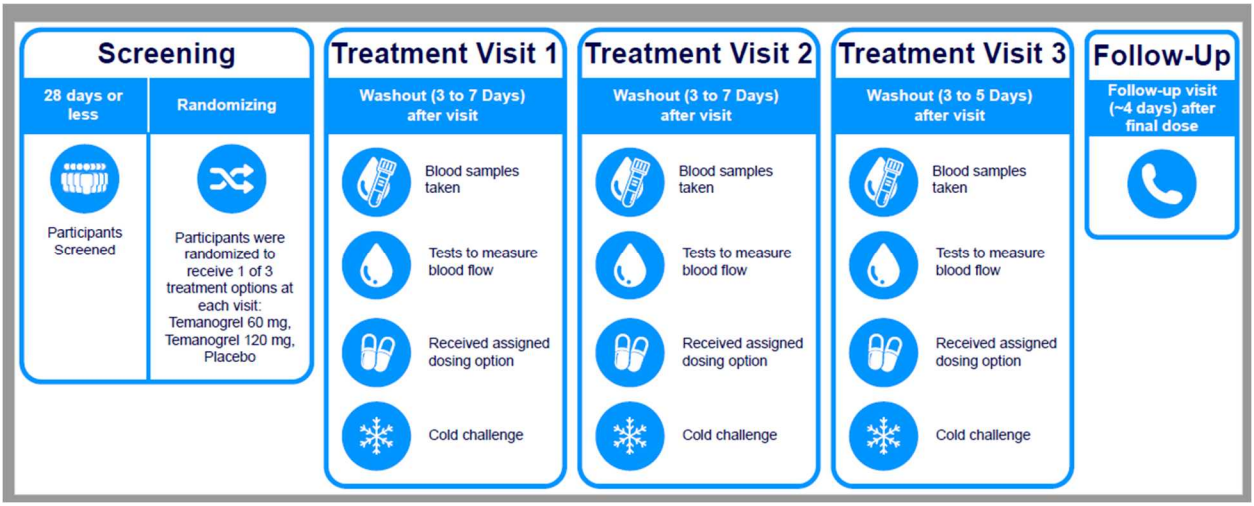
- Temanogrel 60 milligrams (mg)
- Temanogrel 120 mg
- Placebo (A placebo looks just like the study medication but doesn't have any study medication in it)

Each participant was assigned to receive all 3 dosing options one time during the study, but the order in which they received them could vary. At each treatment visit, participants had blood samples taken, had tests to measure blood flow, and received their assigned dosing option. They also had a "cold challenge", in which they were asked to place their hands in cold water for 1 minute, and the tests were then repeated.

Stage B was planned to occur after the researchers evaluated the results from Stage A. However, the study was stopped early for reasons unrelated to safety and no participants were enrolled in Stage B.

This was a double-blind study, which means that the participants, researchers, and study doctors did not know which dosing option the participants received at each visit. Study participants were assigned to each group by chance alone. Participation in this study was expected to last about 6 to 7 weeks, and participants were asked to attend a follow-up telephone visit about 4 days after their final treatment visit.

The figure below shows what happened during the study.



Where did this study take place?

The Sponsor ran this study at 6 study centers in the United Kingdom and the United States.

When did this study take place?

This study began on 20 October 2021, and the Sponsor decided to end the study early, with the study then finishing on 02 September 2022. This was due to a business decision and was not due to any safety concerns about temanogrel. The Sponsor

reviewed the information collected and created a report of the results. This is a summary of that report.

Who participated in this study?

A total of 13 participants joined this study, and all participants (100%) completed study treatment and completed the study. 2 (15%) participants were men and 11 (85%) participants were women. All participants were between the ages of 40 and 70 years.

What were the results of the study?

Did temanogrel improve blood flow in the hands?

Because the Sponsor decided to stop the study early for reasons unrelated to safety, the number of participants was smaller than originally planned and the researchers therefore did not analyse the data as planned. Therefore, the results of the study were inconclusive.

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.

10 out of 13 (77%) participants reported at least 1 medical problem during the study. None of the participants left the study because of medical problems. The table below

shows the most common medical problems—those occurring in at least 2 participants in any group—that happened during the study.

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 at least 2 participants in any group are listed.
- The **2nd** to **4th** column tells how many of the 13 participants reported each medical problem. Next to this number is the percentage of the 13 participants who reported the medical problem.
- Using these instructions, you can see that 1 out of 13 (8%) participants reported headache in the Temanogrel 120 mg group.

Table 1. Commonly reported medical problems by study participants

Medical Problem	Temanogrel 120 mg (13 Participants)	Temanogrel 60 mg (13 Participants)	Placebo (13 Participants)
Headache	1 out of 13 participants (8%)	0 out of 13 participants (0%)	3 out of 13 participants (23%)

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 a serious medical problem, 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.

For more details on your study protocol, please visit:

www.clinicaltrials.gov Use the study identifier **NCT04915950**

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!