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:	APD791-202 (C5071002)
Dates of Study:	20 May 2021 to 31 August 2022
Title of this Study:	A Study Evaluating the Safety, Tolerability, and Effect on Microvascular Obstruction of Intravenous Temanogrel in Adult Participants Undergoing Percutaneous Coronary Intervention [A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety, Tolerability, and Effect on Microvascular Obstruction of Temanogrel in Subjects Undergoing Percutaneous Coronary Intervention]
Date(s) of this Report:	04 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 microvascular obstruction?

Microvascular obstruction (MVO) is the name for a blockage in the small blood vessel(s) that supply the heart with blood. These small blockages can occur during or after a procedure called percutaneous coronary intervention (PCI) that may be performed to treat an existing blockage in the coronary arteries (blood vessel(s) in the heart).

What is temanogrel?

Temanogrel is an investigational treatment that may prevent or reduce MVO. An investigational treatment is one that has not been approved for use outside of a research study. Temanogrel is given through intravenous administration (IV; through a needle in the vein).

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 who are undergoing a PCI procedure.

Researchers wanted to know:

Did temanogrel improve blood flow in the blood vessels of the heart?

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 undergoing a PCI procedure.

Participants included in the study:

- Were examined by a study doctor and determined to be appropriate to participate
- Were 30 to 80 years of age
- Were undergoing PCI to treat one of the following conditions:
    - Stable angina (chest pain with activity or stress)
    - Unstable angina (chest pain at rest)
    - Non-ST-elevation myocardial infarction (NSTEMI; a type of heart attack)

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 done in 2 stages, Stage A and Stage B.

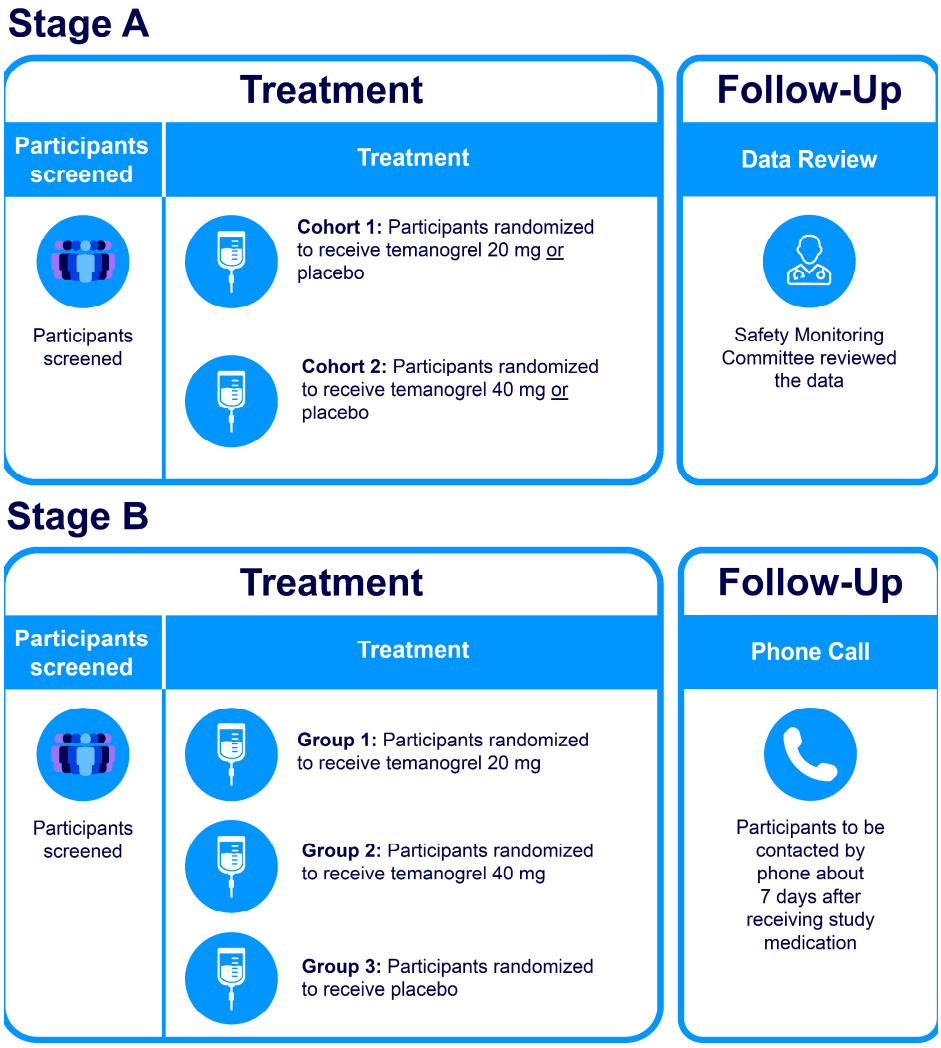
Stage A was planned to include 2 cohorts with 6 participants in each cohort. The first cohort in Stage A was randomized (assigned by chance) to receive one dose of either temanogrel 20 milligrams (mg) or placebo, before their PCI procedure. A placebo looks just like the study medication but doesn't have any study medication in it. A safety monitoring committee reviewed safety information from the first cohort and decided whether to adjust the planned dose for the second cohort in Stage A. The second cohort in Stage A was randomized to receive one dose of temanogrel 40 mg, or placebo before their PCI procedure. The safety monitoring committee then reviewed all the safety information from Stage A to set the doses of temanogrel used in Stage B.

Stage B was planned to include 3 groups of about 29 participants each, but the study was stopped early for reasons unrelated to safety. One group was randomized to receive one dose of temanogrel 20 mg, one group to receive one dose of temanogrel 40 mg, and one group to receive one dose of placebo.

This was a double-blind study, which means that the participants, researchers, and study doctors did not know which treatment the participants received. In addition to temanogrel or placebo, all participants also received dual antiplatelet therapy (DAPT) as part of the standard treatment for people undergoing PCI. DAPT is a combination of two types of medications that both work to prevent blood clots—aspirin and either clopidogrel, ticagrelor, or prasugrel.

Participation in this study was expected to last about 24 days, and participants were contacted by phone about 7 days after they received temanogrel or placebo.

The figure below shows what happened during the study.



Where did this study take place?

The Sponsor ran this study at 12 study centers in Australia, the Netherlands, Sweden, the United Kingdom, and the United States.

When did this study take place?

This study began in May 2021, and the Sponsor decided to end the study early in August 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 29 participants joined this study. 25 (86%) participants were men and 4 (14%) participants were women. All participants were between the ages of 50 and 76.

10 participants were randomized to receive temanogrel 20 mg, 10 participants were randomized to receive temanogrel 40 mg, and 9 participants were randomized to receive placebo. 27 out of 29 (93%) participants received study treatment and completed the study. 2 out of 29 (7%) participants did not receive study treatment and thus left the study early.

What were the results of the study?

Did temanogrel improve blood flow in the blood vessels of the heart?

Because the Sponsor decided to stop the study early, 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.

15 out of 27 (56%) participants who received study treatment reported at least 1 medical problem during the study, including 4 out of 10 (40%) participants who received temanogrel 20 mg, 7 out of 8 (88%) participants who received temanogrel 40 mg, and 4 out of 9 (44%) participants who received placebo. 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 Tables 1 and 2.

Instructions for Understanding Tables 1 and 2.

- 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** column tells how many of the 10 participants who received temanogrel 20 mg reported each medical problem. Next to this number is the percentage of the 10 participants who received temanogrel 20 mg who reported the medical problem.
- The **3rd** column tells how many of the 8 participants who received temanogrel 40 mg reported each medical problem. Next to this number is the percentage of the 8 participants who received temanogrel 40 mg who reported the medical problem.
- The **4th** column tells how many of the 9 participants who received placebo reported each medical problem. Next to this number is the percentage of the 9 participants who received placebo who reported the medical problem.
- Using these instructions, you can see that 0 out of 10 (0%) participants who received temanogrel 20 mg, 2 out of 8 (25%) participants who received temanogrel 40 mg, and 0 out of 9 (0%) participants who received placebo had high blood pressure.

Table 1. Commonly reported medical problems by study participants			
Medical Problem	**Temanogrel 20 mg (10 Participants)**	**Temanogrel 40 mg (8 Participants)**	**Placebo (9 Participants)**
Hematoma (collection of blood outside of blood vessels) at IV site	4 out of 10 participants (40%)	2 out of 8 participants (25%)	1 out of 9 participants (11%)
High blood pressure	0 out of 10 participants (0%)	2 out of 8 participants (25%)	0 out of 9 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. A total of 3 out of 27 (11%) participants who received study treatment reported a serious medical problem during the study. None of these serious medical problems were considered to be related to the study treatment. No participants died during the study. The table below shows the serious medical problems that happened during the study.

Table 2. Serious medical problems reported by study participants			
Serious Medical Problem	**Temanogrel 20 mg (10 Participants)**	**Temanogrel 40 mg (8 Participants)**	**Placebo (9 Participants)**
Heart attack	0 out of 10 participants (0%)	0 out of 10 participants (0%)	1 out of 9 participants (11%)
Hematoma (collection of blood outside of blood vessels) at IV site	0 out of 10 participants (0%)	1 out of 8 participants (13%)	0 out of 9 participants (0%)
Injury to the inner layer of the main artery	0 out of 10 participants (0%)	1 out of 8 participants (13%)	0 out of 9 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.

For more details on your study protocol, please visit:

www.clinicaltrials.gov	Use the study identifier **NCT04848220**
www.clinicaltrialsregister.eu	Use the study identifier **2020-000238-16**

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!