Plain Language Summary of Clinical Study Results

Bristol Myers Squibb™

Short Study Title:	Exploratory Study of Danicamtiv in Patients with Primary Dilated Cardiomyopathy (DCM) Due to Genetic Variants or Other Causalities
Study Medicine:	Danicamtiv (pronounced dan-ih-KAM-tiv), also called BMS-986434
Date of Summary:	22 April 2025

Thank You!

Bristol-Myers Squibb, the sponsor, would like to thank you for participating in this clinical study for a medicine called danicamtiv.

With your help, we learned more about danicamtiv and what effect it has on primary dilated cardiomyopathy.

Overview

In this study, researchers wanted to answer the following questions:

- How safe was danicamtiv for participants with primary dilated cardiomyopathy?
    - Researchers found that the dose levels tested in this study were safe for participants.
- What side effects did participants have during the study?
    - The side effects found in this study matched the known safety profile of study treatment found in other studies.

Why was the study done?

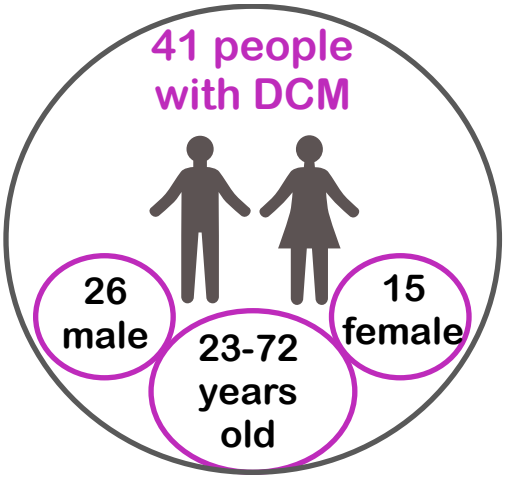
Researchers were looking for a different way to treat primary dilated cardiomyopathy.

Dilated cardiomyopathy (DCM) is a heart condition that causes the heart to enlarge and weaken, making it difficult to pump blood. The researchers wanted to improve how participants' heart muscles work by developing a new treatment to help people with DCM. "Primary" in "primary dilated cardiomyopathy" means that the cause of the dilated cardiomyopathy is unknown or is directly related to a genetic mutation within the heart muscle itself, rather than being caused by a secondary factor like an infection, drug use, or other medical condition. It indicates the heart muscle damage is the primary issue, not a result of another disease.

In this study, researchers wanted to see if danicamtiv was a safe treatment option for participants with DCM. Danicamtiv is a new medicine that works by helping the heart pump better. Previous studies found that danicamtiv made the heart pump stronger without causing problems with how the heart relaxes or handles calcium, which is different from other heart drugs.

Who took part in the study?

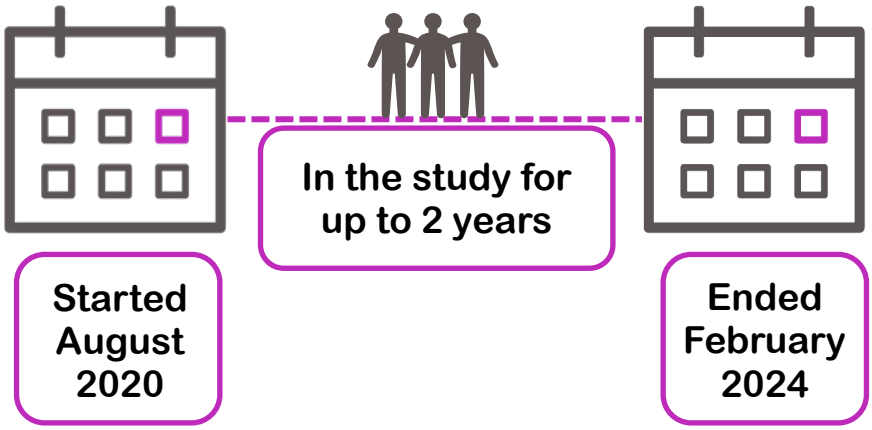
The study included 41 people with DCM who received the study treatment.



- In total, 26 male and 15 female participants took part.
- They were between 23 and 72 years old.
- Part A included 41 participants, 19 of whom also participated in Part B.

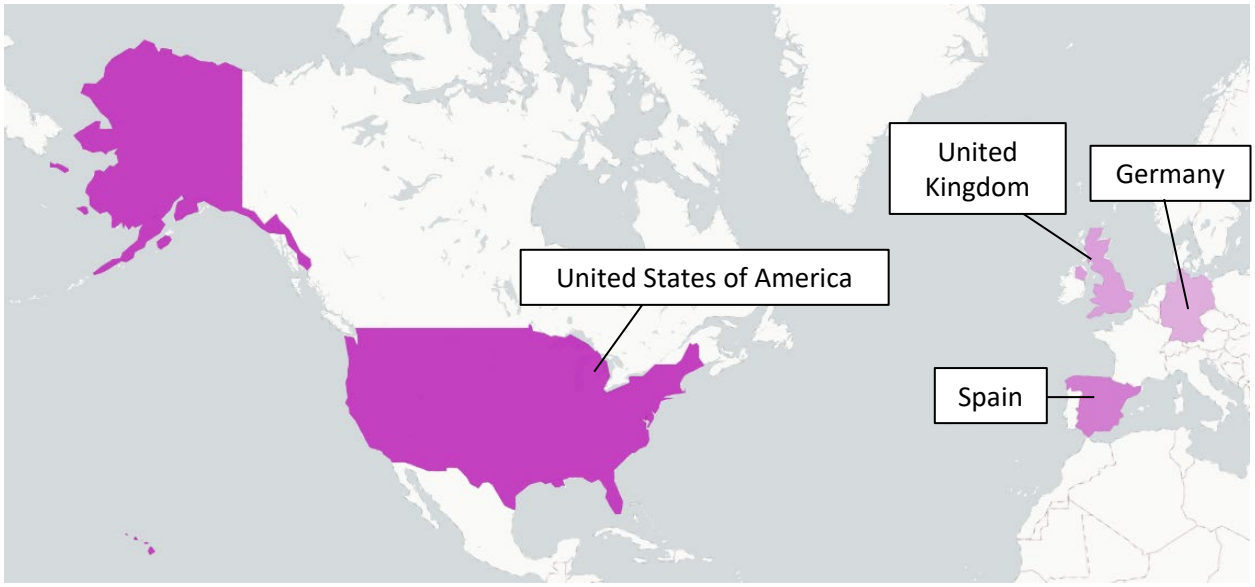
What happened during the study?

The study started in August 2020 and ended in February 2024. The participants were in the study for up to approximately 2 years or until they left the study due to side effects or the study was ended early by the sponsor.



The original plan for this study was for participants to receive treatment during Part A and continue in the study and receive treatment during Part B. However, the sponsor decided to end the study earlier than planned. Because of this, the study ended before participants could finish Part B. The decision to end the study early was made for business reasons and not due to safety concerns.

The map below shows which countries the study participants were from:



What treatments were studied?

All participants received treatment in Part A, as listed below. 19 participants went on to also receive treatment in Part B.

41 participants

Part A

Treatment Period 1

- Participants were given 25 mg of danicamtiv by mouth 2 times a day. Depending on the participant, they received this between 5-8 days.

Treatment Period 2

- Participants were given either 10 mg or 50 mg danicamtiv by mouth 2 times a day. Depending on the participant, they received this between 5-8 days.

19 participants

Part B

- Participants were given 25 mg, 50 mg, or 75 mg of danicamtiv by mouth 2 times a day for up to 2 years.
- Based on the participants' response to the dose during the first 6 weeks, the dose was adjusted as needed.

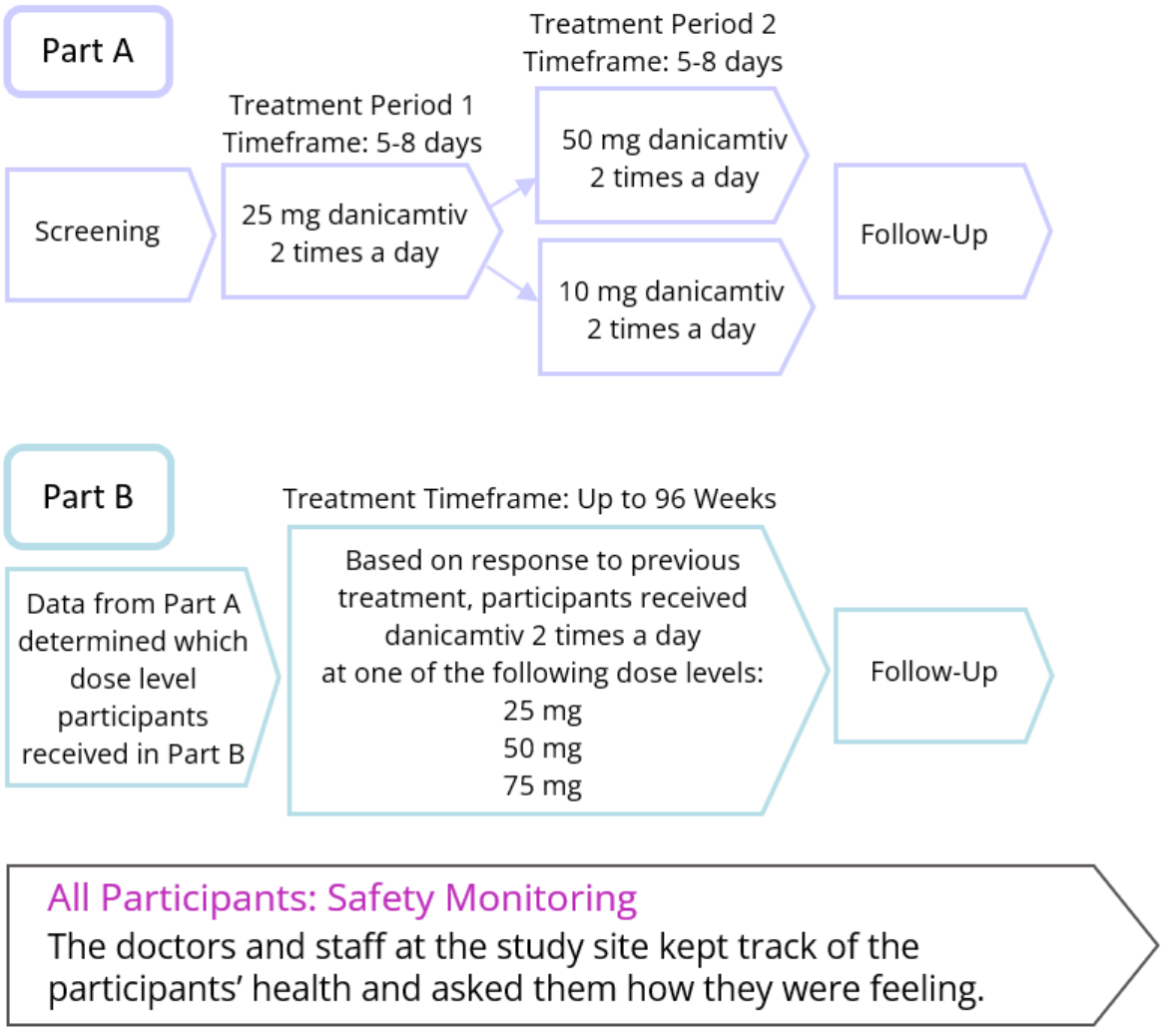
How was the study done?

This section describes what kind of study it was and what happened in the study.

Open-Label

This was an open-label study. This means that the participants, the study doctors, and the other study staff knew which treatments the participants got during the study.

The following graph shows a timeline of what happened during the study:



What were the main results of the study?

This section includes the results of 41 participants who received treatment during the study.

How safe was danicamtiv for participants with primary dilated cardiomyopathy?

The safety of every participant is important throughout the development and testing of study medicines. The study doctors keep a record of all symptoms the participants have during the study.

Symptoms or abnormal findings that study doctors think may or may not be related to treatment are called **"side effects."**

A side effect that can cause death, a life-threatening condition, long-term disability, birth defects (also called congenital defect), needs hospital care, or is considered by the study doctor as medically important is called a **"serious side effect."**

Overall side effects	Part A 41 participants	Part B 19 participants
	Number of participants (%)	
How many participants had any side effects?	6 (15%)	17 (90%)
How many participants had serious side effects?	0 (0%)	5 (26%)
How many participants stopped taking the study medicine because of side effects?	1 (2%)	2 (11%)
How many participants died from side effects?	0 (0%)	0 (0%)

Before the study began, researchers planned to only collect data for the following measurements while the participants were being treated in Part A.

Researchers wanted to know if participants had clinically significant changes in their measurements from the beginning of the study (also called baseline) until the end of the study (follow-up). Clinically significant changes refer to changes in the measurements that are meaningful and important in a medical context, as determined by the study doctors.

Participants with clinically significant change from baseline	**Part A** 41 participants
	Number of participants (%)
How many participants had clinically significant changes from baseline in their physical examinations?	1 (2%)
How many participants had clinically significant changes from baseline in their laboratory values?	6 (5%)
How many participants had clinically significant changes in their electrocardiograms (ECGs)*?	0 (0%)
How many participants had clinically significant changes in their vital signs?	0 (0%)

*ECGs are medical tests that allow the study doctor to check the structure and function of the heart. The technician will apply a gel to the participant's chest and move a device that produces sound waves over their skin. Videos and images of the heart will appear on the computer screen.

What side effects did participants have during the study?

Below is the list of side effects related to the study treatment that were reported. Only 1 or 2 participants experienced each side effect:

- Abdominal pain
- Upper abdominal pain
- Accidentally taking too much medicine, also called an accidental overdose
- Increase in liver function tests, which may be a sign of liver damage

- Cough
- Runny stool, also called diarrhea
- Indigestion, also called dyspepsia
- Discomfort in the muscles, bones, and joints (musculoskeletal)
- Sudden (acute) kidney injury
- Increase in level of an enzyme called creatine phosphokinase, which may mean there has been injury or stress to muscle tissue, the heart, or the brain.
- The feeling of not being able to breathe enough during physical activity, also called dyspnea exertional
- Increase in liver function test
- Liver injury

What were the serious side effects?

Below is the list of serious side effects which may or may not have been related to the study treatment that were reported in Part B. No serious side effects were reported in Part A. 5 participants experienced 7 serious side effects:

- Liver injury
- Sudden (acute) kidney injury
- Worsening of heart failure
- Urinary tract infection
- Life-threatening irregular heart rhythm which required electronic shock treatment, also called ventricular arrhythmia
- Suspected stroke, also called brain ischemic attack

Researchers found no new safety concerns. The side effects found in this study were assessed as not related to the study drug and matched the known safety profile of the medicine found in other studies.

How has this study helped participants and researchers?

You have helped us learn more about the safety of danicamtiv and how it works in participants with dilated cardiomyopathy.

Researchers must look at the results of many studies to decide which treatments work and are safe. This summary includes only the main results from this one study. Other studies may show new information or different results.

There are no more ongoing studies of danicamtiv. If you have questions about the study results or danicamtiv, please speak with a doctor or staff member at the study site. Always talk to a doctor before making any treatment decisions.

Where can I learn more about this study?

You can find more information about this study on the websites listed below.

https://www.clinicaltrials.gov/study/NCT04572893?term=cv028-005&rank=1

https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en&EUCT=2023-505492-68-00

Full Study Title: An Open-Label, Exploratory Study of the Safety and Preliminary Efficacy of Danicamtiv in Stable Ambulatory Participants with Primary Dilated Cardiomyopathy Due to Either MYH7 or TTN Variants or Other Causalities

Study Identification: CV028-005; MYK-491-006

Bristol-Myers Squibb is the sponsor of this study.

For general contact information, go to the link below:

www.globalbmsmedinfo.com