Plain Language Summary of Clinical Study Results

Short Study Title: A Study to Evaluate the Safety, Tolerability and Drug Levels of BMS-986454 in Healthy Participants

Study Medicine: BMS-986454

Date of Summary: 21 November 2025

Thank You!

Bristol-Myers Squibb, the sponsor, would like to thank you for participating in this clinical study for a medicine called BMS-986454.

With your help, we learned more about the safety of BMS-986454 and how it works in the body.

Overview

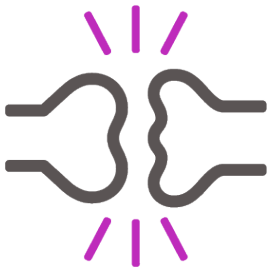
In this study, researchers wanted to answer the following questions:

1. How safe is **BMS-986454** for participants to take?
    - BMS-986454 was mostly safe and did not cause serious problems in healthy adults who took it.



BMS-986454 is a medicine designed to block a substance in the body called PAD4. PAD4 changes proteins in the body that may cause the immune system to attack the joints in people with rheumatoid arthritis.

Why was the study done?



This study looked at a new treatment for rheumatoid arthritis (RA). RA is a disease where the body's defense system (immune system) attacks the joints by mistake. This can cause pain, swelling, and damage to the joints.

What was the study testing?

Researchers think a substance in the body called PAD4 may be part of the problem. PAD4 changes certain proteins, which might cause the immune system to attack the joints. The study tested a new medicine called BMS-986454 which blocks the activity of PAD4, to see if it was safe for healthy participants to take.

Why is this important?

If this medicine works, it could become a new way to treat RA and help people feel better and protect their joints.

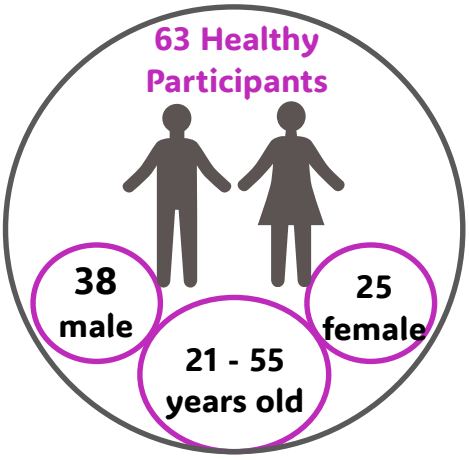


The study tested a new medicine called BMS-986454 to see if it was safe for healthy participants to take.

Who took part in the study?

The study included 63 healthy participants.

- 38 were male and 25 were female.
- They were between 21 and 55 years old.



What happened during the study?

The study started in November 2023 and ended in December 2024.

The participants were in the study for up to 110 days.

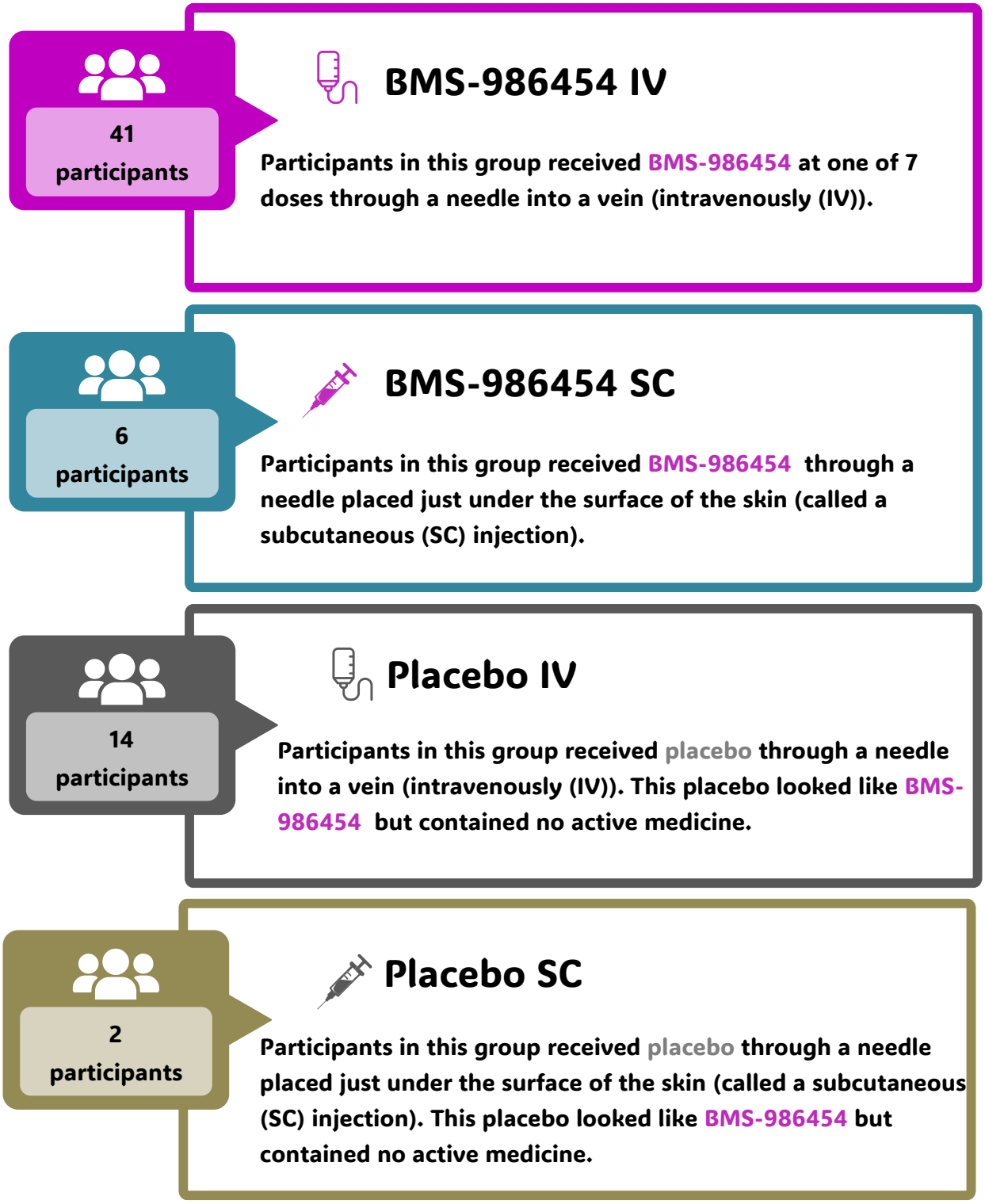


All participants were from the United Kingdom.



What treatments were studied?

Study participants were assigned to one of the treatment groups below.



How was the study done?

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

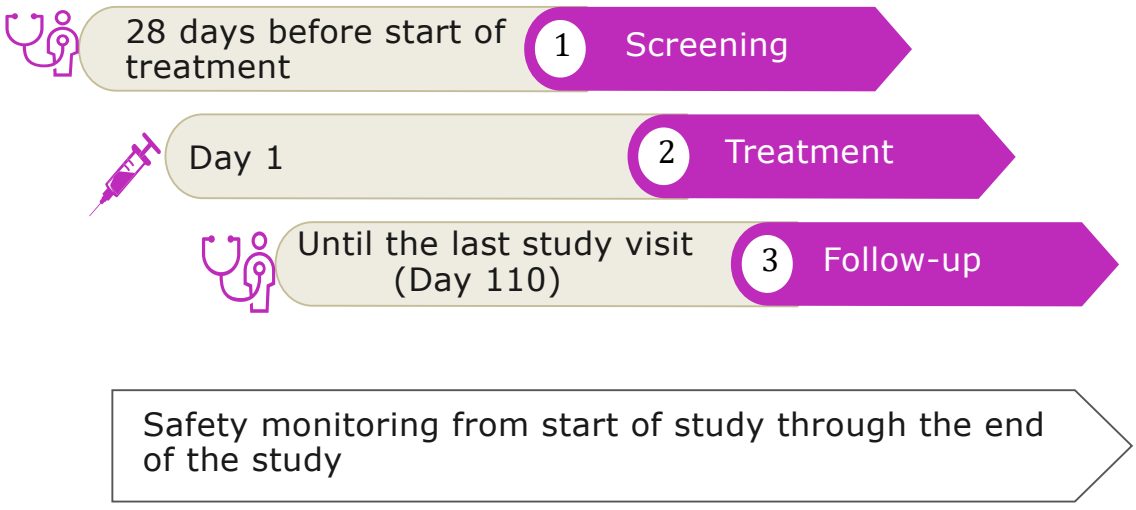
Randomized

Researchers used a computer program to randomly place the participants into a treatment group by chance. This helps to make sure that treatments were chosen fairly.

Double-Blind

This was a double-blind study. This means that the participants, the study doctors, and the other study staff did not know which treatments the participants got during the study.

The diagram below shows what happened during the study.



What were the main safety results of the study?

1. How safe is **BMS-986454** for participants to take?

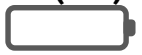
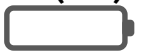
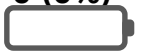
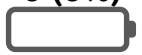
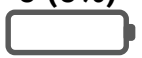
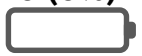
The safety of every participant is important throughout the development and testing of study medicines. The study doctors keep a record of all participants' symptoms during the study.

Side effects are symptoms or abnormal findings that study doctors think may or may not be related to treatment .

A serious side effect is a side effect that may require medical treatment or hospitalization, cause permanent damage, or be life-threatening or sometimes even fatal.

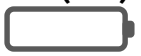
This section includes the results of 63 participants who participated in this study.

The table below shows the number of participants who had side effects that may or may not have been related to study medicine.

Overall side effects	BMS-986454 IV 41 participants	BMS-986454 SC 6 participants	Placebo IV 14 participants	Placebo SC 2 participants
	Number of participants (%)			
How many participants had any side effects related to the study medicine?	4 (10%) 	0 (0%) 	0 (0%) 	0 (0%) 
How many participants had serious side effects?	0 (0%) 	0 (0%) 	0 (0%) 	0 (0%) 
How many participants had any serious side effects related to the study medicine?	0 (0%) 	0 (0%) 	0 (0%) 	0 (0%) 
How many participants stopped taking the study medicine because of side effects?	0 (0%) 	0 (0%) 	0 (0%) 	0 (0%) 
How many participants died from side effects?	0 (0%) 	0 (0%) 	0 (0%) 	0 (0%) 

What were the side effects?

The table below shows the side effects related to the study medicine that were reported during this study.

Side effects	BMS-986454 IV 41 participants	BMS-986454 SC 6 participants	Placebo IV 14 participants	Placebo SC 2 participants
	Number of participants (%)			
Neutropenia, a condition where a person has too few neutrophils (a type of white blood cell).	1 (2%) 	0 (0%) 	0 (0%) 	0 (0%) 
Diplopia, also called double vision, means seeing two images of the same object when you should only see one.	1 (2%) 	0 (0%) 	0 (0%) 	0 (0%) 
Nausea, feeling sick to your stomach and wanting to throw up.	1 (2%) 	0 (0%) 	0 (0%) 	0 (0%) 
Dizziness	1 (2%) 	0 (0%) 	0 (0%) 	0 (0%) 
Headache	1 (2%) 	0 (0%) 	0 (0%) 	0 (0%) 

Hypertransaminasaemia, a condition where there are higher-than-normal levels of certain liver enzymes in the blood. These enzymes—called transaminases—are normally found inside liver cells. When the liver is stressed or damaged, these enzymes can leak into the bloodstream.	**2 (5%)** 	**0 (0%)** 	**0 (0%)** 	**0 (0%)** 

What were the serious side effects?

No serious side effects related to the study medicine were reported during this study.

BMS-986454 was mostly safe and did not cause serious problems in healthy participants who took it.

How has this study helped participants and researchers?

You have helped us learn more about the safety of BMS-986454 and how it works in the body.

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 currently no ongoing studies of BMS-986454 . If you have questions about the study results or BMS-986454 , 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.

Study Details | NCT06086886 | A Study to Evaluate the Safety, Tolerability and Drug Levels of BMS-986454 in Healthy Participants | ClinicalTrials.gov

https://www.clinicaltrials.gov/study/NCT06086886?term=IM055-1001&rank=1

Full Study Title: A Phase 1, Double-blinded, Randomized, Placebo-controlled, First-in-Human Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single and Multiple Doses of BMS-986454 in Adult Participants

Study Identification: IM055-1001

Note: This document was prepared with the aid of artificial intelligence (AI) to ensure clarity and accessibility. It has also undergone an extensive human review and approval process to guarantee accuracy and reliability.

Bristol-Myers Squibb is the sponsor of this study.

For general contact information, go to the link below:

www.globalbmsmedinfo.com