Clinical Study Results Summary

Study Sponsor: Gilead Sciences

Treatment Studied: Remdesivir, also known as Veklury

Study Purpose: To see if remdesivir given for 5 or 10 days could improve the health of study participants with moderate cases of coronavirus disease 2019 (COVID-19). The researchers also wanted to find out if the participants had any side effects during the study.

Thank you

Thank you to the participants who took part in this clinical study for remdesivir, also called Veklury or GS-5734. In addition, thank you to the families, friends, and caregivers of the participants. Gilead Sciences sponsored this study and thinks it is important to share the results with the participants and the public.

If you participated in the study and have questions about the results, please speak with a doctor or staff at a study site.

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Study Overview

What was the purpose of this study?

To see if remdesivir taken for 5 or 10 days could improve the health of study participants with moderate COVID-19. The purpose of this study was also to see if any side effects happen in participants with moderate COVID-19 when treated with remdesivir.

Who was in the study?

- 1,113 participants with moderate COVID-19 in 14 countries around the world
- 26 participants who enrolled but did not take remdesivir were not included in the study results.

What treatments were studied?

There were 2 parts in the study, Part A and Part B.

- In Part A, participants received:
  - Remdesivir for up to 5 days plus standard of care
  - Remdesivir for up to 10 days plus standard of care
  - Standard of care only
- In Part B, participants received:
  - Remdesivir for up to 10 days plus standard of care

Standard of care was the best treatment for COVID-19 that was available to doctors at the time they were treating each participant.

What were the results of the study?

In Part A, participants in the 5-day remdesivir group were 65% more likely to have clinical improvement at Day 11 compared with those in the standard of care group. The 10-day remdesivir treatment group had a similar outcome as the standard of care group.

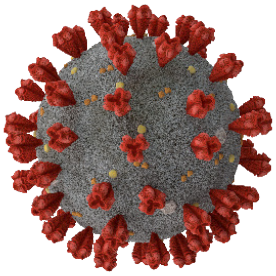
Only Part A was used to evaluate the main results of this study. These results can be found in the “What were the results of the study?” section. Results from Part B are included in all other sections.

For the purpose of this summary, “side effects” are defined as medical problems that the doctors thought might be related to remdesivir. Serious and nonserious side effects happened in about the same number of participants in the 5-day remdesivir treatment group and the 10-day remdesivir treatment group. Participants in the standard of care group did not receive remdesivir, so they could not have any side effects from it.

What was the purpose of the study?

What is COVID-19?

At the end of 2019, a new virus called severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) began to spread around the world. This virus causes coronavirus disease 2019, or COVID-19. The virus spreads through small droplets when infected people cough, sneeze, or breathe out. The symptoms range from mild to very severe and can cause death. Infected people can start having symptoms between 2 and 14 days after they get the virus, while some people have no symptoms. The most common symptoms are fever or chills, cough, difficulty breathing, feeling tired, and headache. Other symptoms include new loss of taste or smell, sore throat, runny nose, throwing up, and diarrhea. These are not the only symptoms of COVID-19.



COVID-19 is especially dangerous for older people and those with other medical problems, such as heart and lung diseases, being overweight, or diabetes. However, the virus is dangerous to everyone, even people who are young and healthy. COVID-19 may cause permanent damage to lungs and other organs. COVID-19 has caused many deaths around the world.

Since COVID-19 is a new disease, researchers are working to find treatments and medications to help people who are infected.

What is remdesivir?

Remdesivir is a prescription medicine used to treat patients with COVID-19 requiring hospitalization.

What were the main questions the researchers wanted to answer?

The main questions the researchers wanted to answer in this study were:

- Could remdesivir improve the health of people with moderate COVID-19?
- Is there a difference in effectiveness between remdesivir taken for 5 days or 10 days with standard of care versus standard of care alone?
- What side effects did the participants have during the study if any?

What kind of study was it?

Phase 3: The researchers wanted to learn how well remdesivir worked in a large number of participants with moderate COVID-19. They also wanted to find out if the participants had any side effects during the study.

Open label study: Each participant knew what they were taking, and the doctors and study staff also knew.

Part A

Randomized study: The researchers used a computer program to randomly choose the treatment each participant took in Part A. This helped make sure the treatments were chosen fairly. The participants had an equal chance of receiving 1 of 3 treatments: remdesivir for 5 days, remdesivir for 10 days, or standard of care alone.

Part B

Single arm: All participants were treated the same way.

Who took part in the study?

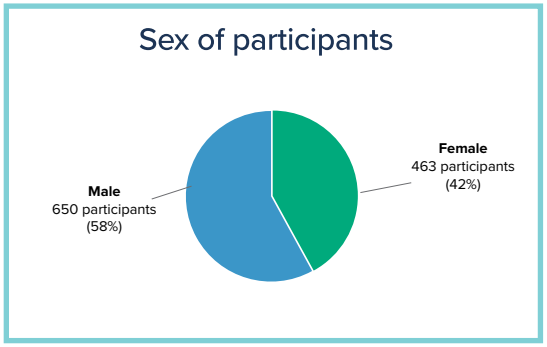
People took part in the study if they:

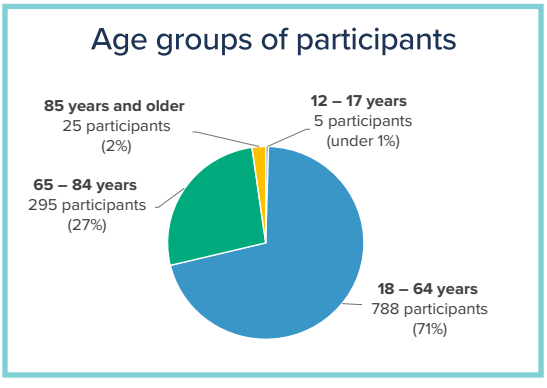
- Were 12 years of age or older
- Had COVID-19 confirmed by lab testing
- Were hospitalized
- Had a blood oxygen saturation level of more than 94% on room air (not on oxygen)
- Had injury to their lungs from COVID-19 that appeared on x-rays or computerized tomography (CT) scans

People who needed life support to help them breathe could not take part in this study.

In total, 1,113 participants with moderate COVID-19 from 14 countries around the world took part in this study.

Country	Number of participants (%)
United States	593 (53%)
Spain	144 (13%)
Italy	134 (12%)
United Kingdom	64 (6%)
South Korea	37 (3%)
Germany	36 (3%)
Singapore	32 (3%)
Hong Kong	28 (3%)
Switzerland	19 (2%)
France	8 (1%)
Taiwan	6 (1%)
Netherlands	5 (under 1%)
Japan	4 (under 1%)
Sweden	3 (under 1%)





Types of breathing help

There are several ways to help patients breathe. These include **oxygen** and **life support**.

- There are many ways to deliver oxygen non-invasively to help raise blood oxygen levels, such as **high and low flow oxygen** through the nostrils and masks.
- **Life support** is invasive because it puts tubes inside the body. Two types of life support that were used in this study are explained below.
  - **Mechanical ventilation** is a type of life support where a tube is placed in the throat and connected to a breathing machine (ventilator) that pushes air into the lungs.
  - **ECMO**, also called extracorporeal membrane oxygenation, provides heart-lung bypass support. It pulls blood out of the body, adds oxygen to it, then pumps the blood back into the body.

The researchers used a scale to keep track of each participant's clinical status. The clinical status included how each participant was doing and what type of treatment was needed.

Only Part A was used to evaluate the main results of this study. There were 12 participants who left the study before taking any study treatment, so here are the clinical status scores for 584 participants in Part A at the beginning of the study.

Part A participants at the beginning of the study				
Score	**Clinical status scale**	**Remdesivir 5 days** (out of 191 participants)	**Remdesivir 10 days** (out of 193 participants)	**Standard of care** (out of 200 participants)
1	Death	0	0	0
2	Hospitalized and on life support	0	0	0
3	Hospitalized and on high-flow oxygen or other non-invasive breathing help	2 (1%)	1 (under 1%)	2 (1%)
4	Hospitalized and on low-flow oxygen	29 (15%)	23 (12%)	36 (18%)
5	Hospitalized and did not need life support or oxygen, but needed medical care	160 (84%)	163 (84%)	160 (80%)
6	Hospitalized but no longer needed medical care	0	6 (3%)	2 (1%)
7	Not hospitalized	0	0	0

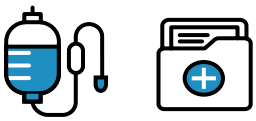
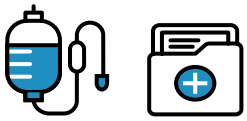
What happened during the study?

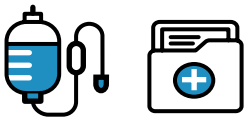
The study started in March 2020 and ended in June 2020.

During the study, participants received:

- Remdesivir as an IV infusion (slow injection into a vein) plus standard of care, or
- Standard of care alone

There were 2 parts to this study: Part A and Part B. There were 26 participants who left the study before taking study treatment: 12 participants in Part A and 14 participants in Part B. The tables below show how they received treatment

Part A	
Group	**Treatment**
 **Remdesivir 5 days** (191 participants)	Remdesivir IV infusion for 5 days plus standard of care. • 200 mg on Day 1 • 100 mg on Days 2 - 5
 **Remdesivir 10 days** (193 participants)	Remdesivir IV infusion for 10 days plus standard of care. • 200 mg on Day 1 • 100 mg on Days 2 - 10
 **Standard of care** (200 participants)	Standard of care was the best treatment for COVID-19 that was available to doctors at the time they were treating each participant.

Part B	
Group	**Treatment**
 **Remdesivir 10 days** (503 participants)	Remdesivir IV infusion for 10 days plus standard of care. • 200 mg on Day 1 • 100 mg on Days 2 - 10

During the study, all participants were checked each day to see how they were responding to treatment for 14 days or until they left the hospital. Their clinical status score was recorded each day. The researchers were most interested in how participants were doing and their clinical status score 11 days after they started the study.

What were the results of the study?

This is a summary of the main results from this study. Only Part A was used to evaluate the main results of this study. This included 584 participants who received remdesivir or standard of care alone.

The main questions that the researchers wanted to answer in this study were:

- Could remdesivir improve the health of people with moderate COVID-19?
- Is there a difference in effectiveness between remdesivir taken for 5 days or 10 days with standard of care versus standard of care alone?
- What side effects did the participants have during the study, if any?

The researchers checked the clinical status for each participant 11 days after they began the study. The table below shows the clinical status scores on Day 11.

Part A participants on Day 11				
Score	**Clinical status scale**	**Remdesivir 5 days** (out of 191 participants)	**Remdesivir 10 days** (out of 193 participants)	**Standard of care** (out of 200 participants)
1	Death	0	2 (1%)	4 (2%)
2	Hospitalized and on life support	0	1 (under 1%)	4 (2%)
3	Hospitalized and on high-flow oxygen or other non-invasive breathing help	5 (3%)	0	7 (4%)
4	Hospitalized and on low-flow oxygen	7 (4%)	12 (6%)	11 (6%)
5	Hospitalized and did not need life support or oxygen, but needed medical care	38 (20%)	44 (23%)	46 (23%)
6	Hospitalized but no longer needed medical care	7 (4%)	9 (5%)	8 (4%)
7	Not hospitalized	134 (70%)	125 (65%)	120 (60%)

The researchers found that:

- Participants in the 5-day remdesivir group were 65% more likely to have clinical improvement at Day 11 compared with those in the standard of care group.
- The 10-day remdesivir treatment had a similar effect on clinical status compared to standard of care.

What side effects happened during the study?

For the purpose of this summary, “side effects” are defined as medical problems that the doctors thought might be related to remdesivir. A side effect is considered “serious” if it results in death, is life-threatening, or considered by the doctor to be medically important. Side effects are also serious if they cause lasting problems or require hospital care. All other side effects are considered “non-serious”.

The results from several studies are usually needed to help decide if a treatment actually causes a side effect.

There were 26 participants who did not take any study treatment. So, the results in this section only include 887 participants who received remdesivir. Participants in the standard of care group did not receive remdesivir, so they could not have any side effects from it.

The table below shows how many participants had side effects during the study.

	Part A		Part B
	Number of participants (%)		
Overall side effects	**Remdesivir 5 days** (out of 191 participants)	**Remdesivir 10 days** (out of 193 participants)	**Remdesivir 10 days** (out of 503 participants)
How many participants had serious side effects?	1 (under 1%)	0	1 (under 1%)
How many participants had non-serious side effects?	36 (19%)	25 (13%)	83 (17%)
How many participants died from side effects?	0	0	0
How many participants stopped taking the study treatments because of side effects?	4 (2%)	4 (2%)	12 (2%)

The table below shows all the serious side effects that happened during the study.

Serious side effects	Part A		Part B
	Number of participants (%)		
	Remdesivir 5 days (out of 191 participants)	**Remdesivir 10 days** (out of 193 participants)	**Remdesivir 10 days** (out of 503 participants)
Slow heartbeat (heart rate decreased)	1 (under 1%)	0	0
Low blood pressure (hypotension)	0	0	1 (under 1%)

The table below shows the 5 most common non-serious side effects that happened during the study. Some participants may have had more than 1 non-serious side effect.

The most common non-serious side effects were nausea and increased level of alanine aminotransferase (ALT) and aspartate aminotransferase (AST), liver proteins in the blood. An increase in liver protein in the blood can sometimes mean that the liver is injured or inflamed.

Most common non-serious side effects	Part A		Part B
	Number of participants (%)		
	Remdesivir 5 days (out of 191 participants)	**Remdesivir 10 days** (out of 193 participants)	**Remdesivir 10 days** (out of 503 participants)
Nausea	13 (7%)	7 (4%)	20 (4%)
Increased level of liver protein in the blood (ALT increased)	7 (4%)	4 (2%)	17 (3%)
Increased level of liver protein in the blood (AST increased)	5 (3%)	4 (2%)	14 (3%)
Headache	4 (2%)	3 (2%)	5 (under 1%)
Increased level of liver protein in the blood (transaminases increased)	0	1 (under 1%)	10 (2%)

How has this study helped researchers?

The researchers learned more about the safety and effectiveness of remdesivir compared to standard of care as a treatment for people with moderate COVID-19.

The results from several studies are needed to help decide which treatments work and are safe. This summary shows only the main results from this one study. Other studies may provide new information or different results. Always talk to a doctor before making any treatment changes.

Further clinical studies with remdesivir are planned.

Where can I learn more about this study?

You can find more information about this study on the websites listed below. If a full summary of the study's results is available, it might be on these websites:

- www.clinicaltrials.gov Once you are on the website, type **"NCT04292730"** into the search box and click **"Search"**
- www.clinicaltrialsregister.eu Once you are on the website, click **"Home and Search"**, then type **"2020-000842-32"** into the search box and click **"Search"**

Short study title: Study to Assess the Safety and Effectiveness of Remdesivir in People with Moderate COVID-19

Full study title: A Phase 3 Randomized Study to Evaluate the Safety and Antiviral Activity of Remdesivir (GS-5734™) in Participants with Moderate COVID-19 Compared to Standard of Care Treatment

Gilead Protocol Number: GS-US-540-5774

National Clinical Trials Number: NCT04292730

EU Clinical Trials Number: 2020-000842-32

Gilead Sciences sponsored this study and has its headquarters at 333 Lakeside Drive, Foster City, CA 94404, USA.

The phone number for the Gilead Clinical Study Information Center is 1-833-GILEAD-0 (1-833-445-3230).

The email address for the Gilead Clinical Study Information Center is GileadClinicalTrials@gilead.com.

This summary was created and approved by Gilead Sciences on 07 December 2020. The information in this summary does not include any information available after this date.

Thank You

Clinical study participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.