



# CLINICAL STUDY RESULTS SUMMARY



**Study Sponsor:** Gilead Sciences

**Treatment Studied:** Remdesivir, also known as Veklury

**Gilead Protocol Number:** GS-US-540-5912

**Dates of Trial:** March 2021 to May 2022

**Short Study Title:** Study of remdesivir in people with kidney problems who were hospitalized for COVID-19

**Study Nickname:** REDPINE

## Thank you

Thank you to the participants who took part in the clinical study for **remdesivir**, also known as **Veklury or GS-5734**.



Gilead Sciences sponsored this study. We believe it is important to share the results with the participants and the general public.

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

Always talk to a doctor before making any treatment changes.

**Date of this Report:** March 2023

The information in this summary does not include any information available after this date. This document is a short summary of this study written for a general audience. Links to scientific summaries of this study can be found at the end of this document.



# 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. While this disease can affect breathing in people, it can also damage other organs in the body. The virus spreads through small droplets when infected people cough, sneeze, or breathe out.

The symptoms range from mild to very severe, and the virus 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, muscle or body aches, and diarrhea. These are not the only symptoms of COVID-19. Researchers are still learning about COVID-19.

COVID-19 is more likely to be dangerous for older people and those with other medical problems. These other medical problems can include heart and lung diseases, being overweight, having diabetes or kidney problems. However, the virus can be dangerous to everyone, even people who are young and healthy. COVID-19 may cause **permanent damage to the lungs and other organs**. It has caused many deaths around the world.

COVID-19 infection can be more severe in patients with kidney problems. One complication of COVID-19 is **acute kidney injury**. Acute kidney injury is when the kidneys suddenly fail or become damaged over several hours or days. This makes it hard for the kidney to properly control the amount of fluids in the body.

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

## What is remdesivir?

Remdesivir is a prescription medicine used for the treatment of coronavirus disease 2019 (COVID-19) in adults and children 28 days of age and older and weighing at least 7 pounds (3 kg) who are:

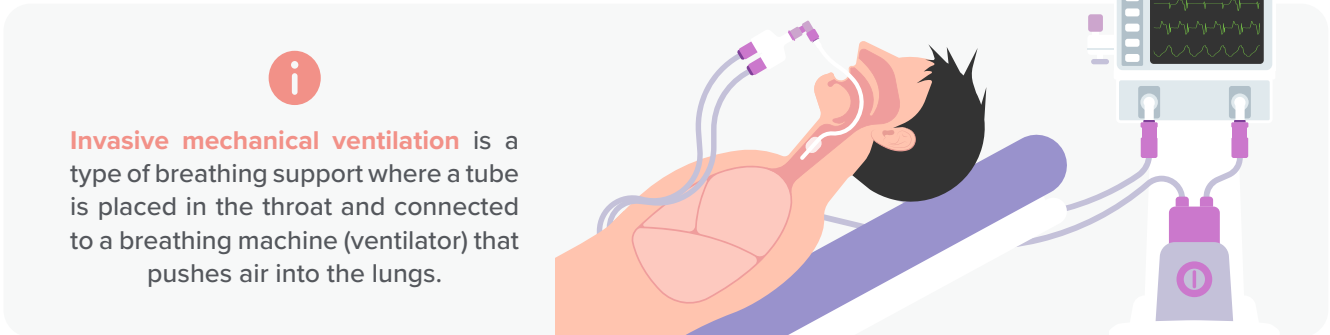
- Hospitalized, or
- Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

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

For the participants with COVID-19 who had kidney problems and were hospitalized:

- Did remdesivir reduce the risk of death or needing **invasive mechanical ventilation** in the first 29 days after starting treatment as compared to **placebo**?
- What side effects did participants have during the study, if any?

**i** A **placebo** looks like a treatment but does not have any drug in it. Researchers use a placebo as a point of comparison to identify whether a new treatment is effective and safe.





# Who took part in the study?

The participants who took part in this study had kidney problems and were hospitalized for COVID-19. The study enrolled **249 participants from 5 countries** around the world.

People took part in the study if they:



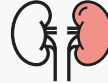
Were 12 years of age or older



Were hospitalized due to a known COVID-19 infection



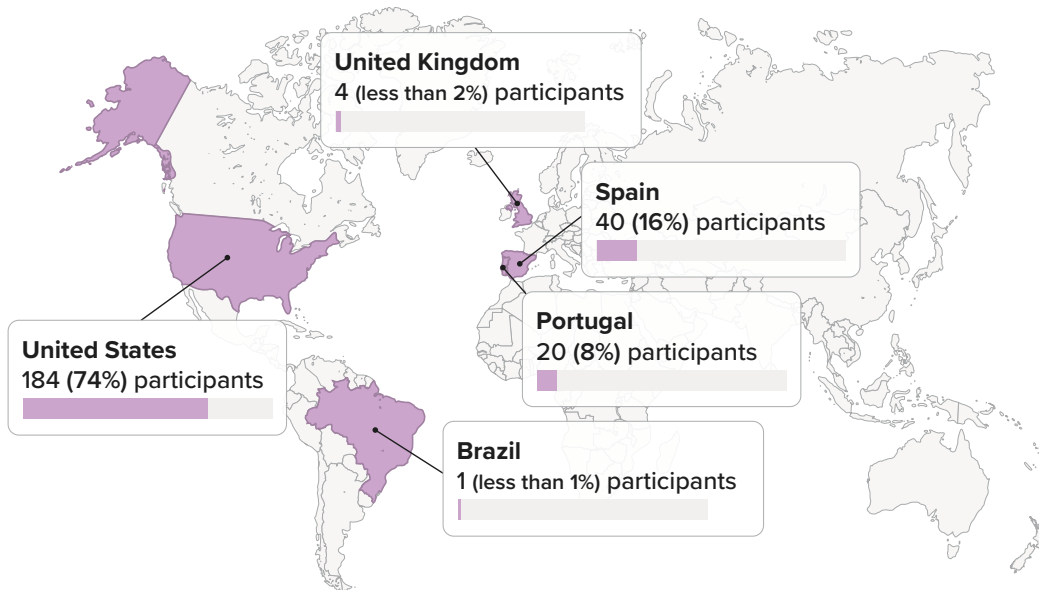
Had a blood oxygen level of 94% or less on room air or needed help breathing with oxygen



Had low kidney function or acute kidney injury

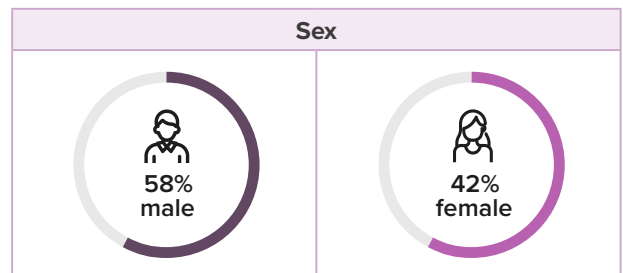
Participants 12 years of age or older were allowed to take part in the study. However, only participants between the ages of **34 and 100 years old** actually took part.

The map below shows how many participants were from each country.



The tables below show the sex, race, and ethnicity of participants who were included in this study.

Race	Number of participants (%)
White	162 (65%)
Black or African American	63 (25%)
Other	12 (5%)
Asian	6 (2%)
Not allowed to collect	4 (2%)
American Indian or Alaska Native	1 (less than 1%)
Native Hawaiian or Other Pacific Islander	1 (less than 1%)



Ethnicity	Number of participants (%)
Not Hispanic or Latino	211 (85%)
Hispanic or Latino	33 (13%)
Not allowed to collect	5 (2%)

## ? What happened during the study?

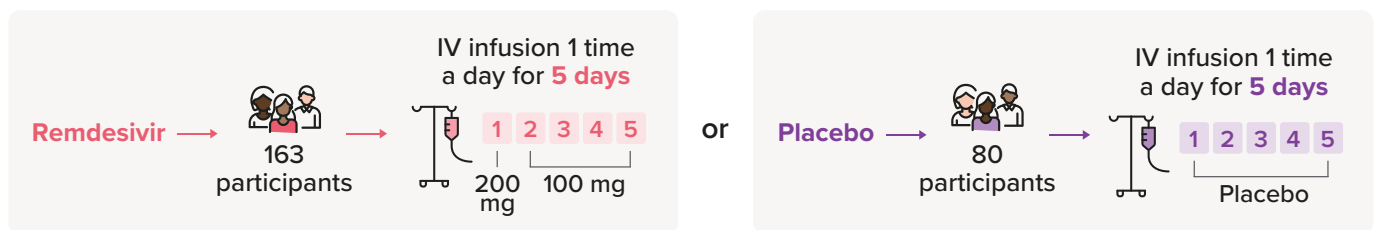
The study was **randomized**, which means that the researchers used a computer program to randomly choose the treatment each participant took. This helped make sure the treatments were chosen fairly. In this study, participants **continued to receive standard of care** and had a 67% percent chance of receiving remdesivir and a 33% chance of receiving placebo.

Standard of care was the best treatment for participants with kidney problems and COVID-19 that was available to researchers at the time they were treating each participant.

**During the study**, in addition to standard of care, participants received either:

- **Remdesivir** as an intravenous (IV) infusion (slow injection into a vein), or
- **Placebo** as an IV infusion

The graphic below shows the treatment the participants took:



None of the participants, doctors, or other study staff knew what treatment each participant took.

Participants received treatment for 5 days. During the study, all participants were checked each day to see how they were responding to treatment for 29 days or until they left the hospital. They had a follow-up phone call on Day 60.

This study was stopped early after 249 participants were enrolled. The decision to stop the study was not because of any concerns with the safety or how well the drug worked. Gilead decided to stop the study in March 2022, as it was hard to find people who could take part in this study.

## 📊 What were the results of the study?

No results about how good the study treatment was at preventing death or invasive mechanical ventilation are given because the study stopped early and there is not enough information for researchers to make any conclusions.



## What side effects did participants have during the study?

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

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

There were 6 participants who did not take any study treatment. So, the results in this section only include 243 participants. **No participants died from side effects or had any serious side effects.**

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

Overall side effects			
	Remdesivir (out of 163 participants)	Placebo (out of 80 participants)	Total (out of 243 participants)
	Number of participants (%)		
How many participants had any side effects?	13 (8%)	3 (4%)	16 (7%)
How many participants stopped taking study treatment because of side effects?	1 (less than 1%)	0	1 (less than 1%)

The table below shows the **6 most common side effects** that occurred during the study. There were other side effects, but those occurred in fewer participants. Some participants may have had more than 1 side effect.

The most common side effect was increased level of pancreatic enzyme in the blood (lipase).

Most common side effects			
	Remdesivir (out of 163 participants)	Placebo (out of 80 participants)	Total (out of 243 participants)
	Number of participants (%)		
Increased level of pancreatic enzyme in the blood (lipase)	2 (1%)	1 (1%)	3 (1%)
Belly pain	2 (1%)	0	2 (less than 1%)
Increased level of liver protein in the blood (alanine aminotransferase)	2 (1%)	0	2 (less than 1%)
Increased level of liver protein in the blood (aspartate aminotransferase)	2 (1%)	0	2 (less than 1%)
Diarrhea	2 (1%)	0	2 (less than 1%)
Nausea	2 (1%)	0	2 (less than 1%)





## How has this study helped researchers?

Even though the study ended early, it helped researchers learn more about the safety of remdesivir in people with COVID-19 and kidney problems.

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.

Gilead Sciences does plan to have further clinical studies with remdesivir.



## Where can I learn more about this study?

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

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)



Once you are on this website, type **NCT04745351** into the search box and click **Search**

[www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu)



Once you are on the website, click **Home and Search**, then type **2020-005416-22** into the search box and click **Search**

[www.gileadclinicaltrials.com](http://www.gileadclinicaltrials.com)



Once you are on the website, type **GS-US-540-5912** into the search box and click **Search Now**

**National Clinical Trials Number:** NCT04745351

**EU Clinical Trials Number:** 2020-005416-22

**Full Study Title:** A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter Study Evaluating the Efficacy and Safety of Remdesivir in Participants with Severely Reduced Kidney Function who are Hospitalized for COVID-19

For more information about clinical trials, [click here](#).

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## 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.

