

# Study to assess the safety and effectiveness of remdesivir in people with severe COVID-19

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
29/10/2020	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
03/11/2020	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
19/03/2021	Infections and Infestations	

## Plain English summary of protocol

### Background and study aims

The purpose of this study is to test a new medicine, remdesivir (RDV) for people with COVID-19. There are no approved medications to treat COVID-19, a new disease caused by a virus called SARS-CoV-2 that was just identified in late 2019. COVID-19 can cause many symptoms. The symptoms can range from mild to very severe and sometimes can lead to death. The purpose of this study is to see if RDV can improve the health of people with severe COVID-19.

### Who can participate?

Persons 12 years of age or older who have SARS-CoV-2 infection less than 4 days before joining the study, and are in hospital

### What does the study involve?

Part A of this study included approximately 400 participants with severe COVID-19 infection. Part B of this study included approximately 5,600 participants also with severe COVID-19 infection. The treatment assignment for participants in Part B was based on whether or not they were on mechanical ventilation. The study doctor conducted a screening visit to make sure they could join the study.

#### Part A

Randomized study: The researchers used a computer program to randomly choose the treatment each participant took. This helped make sure the treatments were chosen fairly. Participants had an equal chance of receiving RDV for 5 days or RDV for 10 days. In both treatment arms, participants still received standard of care treatment.

Open label study: Each participant knew which treatment length they would get and the doctors and study staff also knew.

#### Part B was also open-label.

Participants who qualified for the study and decided to join received RDV by injections directly into the vein

Participants were followed up for 10 days.

## What are the possible benefits and risks of participating?

Possible benefits: Participants may not get any benefit from taking part in this study. Studies are a way for doctors to see if a drug is useful in treating a disease. Taking part in this study may help us know more about how to treat people with COVID-19 in the future.

Possible risks: All medicines could potentially cause side effects in some people. Increases in levels of liver enzymes have been seen in some people who have taken RDV, which may be a sign of inflammation or damage to the cells in the liver.

## Where is the study run from?

The study was run from Gilead Sciences, Inc. (USA) and took place at 173 centres globally.

## When is the study starting and how long is it expected to run for?

February 2020 to June 2020

## Who is funding the study?

Gilead Sciences, Inc. (USA)

## Who is the main contact?

GileadClinicalTrials@gilead.com

# Contact information

## Type(s)

Scientific

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# Additional identifiers

## Clinical Trials Information System (CTIS)

2020-000841-15

## Integrated Research Application System (IRAS)

282007

## ClinicalTrials.gov (NCT)

NCT04292899

## Protocol serial number

GS-US-540-5773, IRAS 282007, CPMS 45460

# Study information

## Scientific Title

A phase 3 randomized study to evaluate the safety and antiviral activity of Remdesivir (GS-5734™) in participants with severe COVID-19

## Study objectives

The odds of improvement for the 5-day treatment group (Treatment Group 1) is different from the odds of improvement for the 10-day treatment group (Treatment Group 2) with respect to clinical status assessed by a 7-point ordinal scale on Day 14

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 25/03/2020, North East - Tyne & Wear South Research Ethics Committee (HRA Jarrow, Room 001, Jarrow Business Centre, Rolling Mill Road, Jarrow, NE32 3DT, UK; +44 (0)207 1048084; nrescommittee.northeast-tyneandwearsouth@nhs.net), ref: 20/NE/0104

## Study design

Phase 3 randomized open-label multi-center study

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

COVID-19 (SARS-CoV-2 infection)

## Interventions

The study was conducted in two parts.

In Part A, approximately 400 participants who met all eligibility criteria and who were not mechanically ventilated were randomized via an interactive web response system (IWRS) in a 1:1 ratio into one of the following treatment groups:

Treatment Group 1: continued standard of care therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2, 3, 4, and 5

Treatment Group 2: continued standard of care therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2, 3, 4, 5, 6, 7, 8, 9, and 10

After Part A completed enrollment, Part B enrolled up to 5600 additional participants, including some who were on mechanical ventilation. In Part B, participants who met all of the eligibility criteria were enrolled to receive the following (based on whether they were mechanically ventilated at enrollment):

Mechanically Ventilated Treatment Group: continued standard of care therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2, 3, 4, 5, 6, 7, 8, 9, and 10

Extension Treatment Group: continued standard of care therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2, 3, 4, 5, 6, 7, 8, 9, and 10

If the 5-day dosing regimen used in Treatment Group 1 of Part A is selected for Part B, all participants in the Extension Treatment Group and all new participants will be reassigned to receive treatment for a total of 5 days. National and local regulatory authorities will be informed.

All participants were followed-up for 28 days.

### **Intervention Type**

Drug

### **Phase**

Phase III

### **Drug/device/biological/vaccine name(s)**

Remdesivir (RDV)

### **Primary outcome(s)**

The odds of ratio for improvement on a 7-point ordinal scale on day 14, calculated from daily scores taken each day from baseline to day 14. (The ordinal scale is an assessment of the clinical status at a given day. The scale is as follows: 1. Death 2. Hospitalized, on invasive mechanical ventilation or Extracorporeal Membrane Oxygenation (ECMO) 3. Hospitalized, on non-invasive ventilation or high flow oxygen devices 4. Hospitalized, requiring low flow supplemental oxygen 5. Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (coronavirus (COVID-19) related or otherwise) 6. Hospitalized, not requiring supplemental oxygen - no longer required ongoing medical care (other than per protocol Remdesivir administration 7. Not hospitalized)

### **Key secondary outcome(s)**

Adverse Events recorded from patient medical records from the time of consent up to Day 28 (+/-5 days). Serious adverse events were reported up to 30 days of last dose and after the protocol defined follow-up period if deemed relevant to the use of study drug.

### **Completion date**

30/06/2020

## **Eligibility**

### **Key inclusion criteria**

1. Willing and able to provide written informed consent, or with a legal representative who can provide informed consent, or enrolled under ICH E6(R2) 4.8.15 emergency use provisions as deemed necessary by the investigator (participants  $\geq$  18 years of age), or willing and able to provide assent (participants  $\geq$  12 and  $<$  18 years of age, where locally and nationally approved) prior to performing study procedures. For participants  $\geq$  12 and  $<$  18 years of age, a parent or legal guardian willing and able to provide written informed consent prior to performing study procedures
2. Aged  $\geq$  18 years (at all sites), or aged  $\geq$  12 and  $<$  18 years of age weighing  $\geq$  40 kg (where permitted according to local law and approved nationally and by the relevant institutional review board [IRB] or independent ethics committee [IEC])
3. SARS-CoV-2 infection confirmed by PCR test  $\leq$  4 days before randomization
4. Currently hospitalized
5. SpO<sub>2</sub>  $\leq$  94% on room air or requiring supplemental oxygen at screening
6. Radiographic evidence of pulmonary infiltrates

7. Men and women of childbearing potential who engage in heterosexual intercourse must agree to use protocol specified method(s) of contraception

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Other

**Sex**

All

**Total final enrolment**

4891

**Key exclusion criteria**

1. Participation in any other clinical trial of an experimental treatment for COVID-19
2. Concurrent treatment with other agents with actual or possible direct-acting antiviral activity against SARS-CoV-2 <24 hours prior to study drug dosing
3. Evidence of multiorgan failure
4. Mechanically ventilated (including V-V ECMO)  $\geq 5$  days, or any duration of V-A ECMO
5. ALT or AST  $>5$  ULN
6. Creatinine clearance  $<50$  mL/min using the Cockcroft-Gault formula for participants  $\geq 18$  years of age and Schwartz Formula for participants  $<18$  years of age
7. Positive pregnancy test
8. Breastfeeding woman
9. Known hypersensitivity to the study drug, the metabolites, or formulation excipient

**Date of first enrolment**

06/03/2020

**Date of final enrolment**

29/05/2020

## Locations

**Countries of recruitment**

United Kingdom

England

Scotland

France

Germany

Hong Kong

Italy

Japan

Korea, South

Netherlands

Singapore

Spain

Sweden

Switzerland

Taiwan

United States of America

Uruguay

**Study participating centre**

**Prince of Wales Hospital**

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Sha Tin

Hong Kong

Hong Kong

-

**Study participating centre**

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Kowloon

Hong Kong

Hong Kong

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Korea, South  
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**Study participating centre**  
**National Medical Center**  
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4564

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**Singapore General Hospital (SGH)**  
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Service des maladies infectieuses et tropicales,  
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3075

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2nd Floor  
Dallas, TX  
United States of America  
75235

**Study participating centre**

**UT Southwestern Medical Center-ID Clinical Research**  
1936 Amelia Court  
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Dallas, TX  
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75235

**Study participating centre**

**Holy Cross Hospital**  
1500 Forest Glen Road,  
Silver Spring, Maryland  
United States of America  
20910

**Study participating centre**  
**Franciscan Health System Research Center**  
1708 South Yakima Avenue, Suite 300,  
Tacoma, Washington  
United States of America  
98405

**Study participating centre**  
**University of Michigan**  
1500 East Medical Center Drive, Ann Arbor,  
Michigan  
United States of America  
48109

**Study participating centre**  
**Inova Fairfax Hospital**  
3300 Gallows Road,  
Falls Church, Virginia  
United States of America  
22042

**Study participating centre**  
**Sutter Medical Center Sacramento**  
2825 Capitol Avenue,  
Sacramento, California  
United States of America  
95816

**Study participating centre**  
**Sutter Roseville Medical Center**  
One Medical Plaza  
Roseville, CA  
United States of America  
95661

**Study participating centre**

**Jacobi Medical Center**

1400 Pelham Parkway South, Bronx, New York  
United States of America  
10461

**Study participating centre**

**California Pacific Medical Center**  
1101 Van Ness Avenue, San Francisco,  
California  
United States of America  
94109

**Study participating centre**

**Virginia Mason Medical Center**  
1100 9th Avenue,  
Seattle, Washington  
United States of America  
98101

**Study participating centre**

**Tacoma General Hospital**  
315 Martin Luther King Jr Way ,Tacoma, Washington  
United States of America  
98405

**Study participating centre**

**Liver Institute at Methodist Dallas**  
1411 North Beckley Avenue, Pavillion III,  
Suite 268, Dallas,  
Texas  
United States of America  
75203

**Study participating centre**

**New York Presbyterian Hospital - Weill-Cornell**  
525 East 68th Street,  
New York  
United States of America  
10065

**Study participating centre**

**Brigham and Womens Hospital**

75 Francis Street, Division of Infectious Disease,  
Brigham and Women's Hospital, Boston, Massachusetts  
United States of America  
2115

**Study participating centre**

**Alta Bates Summit Medical Center**

2450 Ashby Avenue,  
Berkeley, California  
United States of America  
94705

**Study participating centre**

**Virginia Hospital Center**

1701 North George Mason Drive,  
Arlington, Virginia  
United States of America  
22205

**Study participating centre**

**Kaiser Permanente**

Skyline Medical Office  
1375 East 20th Avenue  
Denver, CO  
United States of America  
80204

**Study participating centre**

**Kaiser Permanente Center For Health Research**

3800 North Interstate Avenue, Portland,  
Oregon  
United States of America  
97227

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**Kiaser Westside Medical Center**  
2875 NW Stucki Ave., Hillsboro, OR  
United States of America  
97124

**Study participating centre**  
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5841 S. Maryland Ave.,  
Chicago, Illinois  
United States of America  
60637

**Study participating centre**  
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110 Rehill Avenue,  
Somerville, New Jersey  
United States of America  
8876

**Study participating centre**  
**Robert Wood Johnson University Hospital New Brunswick**  
1 RWJ Place  
New Brunswick, NJ  
United States of America  
08901

**Study participating centre**  
**Newark Beth Isreael Medical Center**  
201 Lyons Avenue  
Newark, NJ  
United States of America  
07112

**Study participating centre**  
**Danbury Hospital**  
24 Hospital Avenue,  
Danbury, Connecticut  
Uruguay  
6810

**Study participating centre**  
**Columbia University Medical Center**  
622 W 168th St,  
PH E101, New York  
United States of America  
10032

**Study participating centre**  
**Yale-New Haven Hospital**  
20 York St, New Haven,  
Connecticut  
United States of America  
06510-3220

**Study participating centre**  
**Tufts Medical Center – PPDS**  
800 Washington Street, Boston,  
Massachusetts  
United States of America  
2111

**Study participating centre**  
**Providence Saint Vincent's Medical Center**  
9205 Southwest Barnes Road, Portland,  
Oregon  
United States of America  
97225

**Study participating centre**  
**St Joseph's Regional Medical Center**  
703 Main Street,  
Paterson, New Jersey  
United States of America  
7503

**Study participating centre**  
**Mayo Clinic – PPDS**  
200 First Street Southwest, Rochester,

Minnesota  
United States of America  
55905

**Study participating centre**  
**Hoag Memorial Hospital Presbyterian**  
One Hoag Drive, Newport Beach,  
California,  
United States of America  
92663

**Study participating centre**  
**Virginia Commonwealth University**  
1250 East Marshall Street,  
Richmond, Virginia  
United States of America  
23298

**Study participating centre**  
**Maine Medical Center**  
22 Bramhall Street,  
Portland, Maine  
United States of America  
4102

**Study participating centre**  
**Eden Medical Center**  
20103 Lake Chabot Road,  
Castro Valley,  
California  
United States of America  
94546

**Study participating centre**  
**Rush University Medical Center**  
1653 W. Congress Parkway, Chicago,  
Illinois  
United States of America  
60612

**Study participating centre**

**Kaiser Permanente Oakland Medical Center**  
3600 Broadway,  
Oakland, California  
United States of America  
94611

**Study participating centre**

**Kaiser Permanente San Francisco Medical Center**  
2425 Geary Blvd. San Francisco, CA  
United States of America  
94115

**Study participating centre**

**Kaiser Permanente South San Francisco Medical Center**  
1200 El Camino Real, San Francisco, CA  
United States of America  
94080

**Study participating centre**

**Kaiser Permanente San Jose Medical Center**  
250 Hospital Parkway, San Jose, CA  
United States of America  
95119

**Study participating centre**

**Kaiser Permanente San Leandro Medical Center**  
2500 Merced Street San Leandro, CA  
United States of America  
94577

**Study participating centre**

**Kaiser Permanente Santa Clara**  
700 Lawrence Expressway, Santa Clara, CA  
United States of America  
95051

**Study participating centre**

**Providence St Peter Hospital**  
, 413 Lilly Road Northeast, Olympia,  
Washington  
United States of America  
98506

**Study participating centre**  
**Beth Israel Deaconess Medical Center**  
330 Brookline Avenue,  
Boston, Massachusetts  
United States of America  
2215

**Study participating centre**  
**Stanford University School of Medicine**  
300 Pasteur Drive,  
Stanford, California  
United States of America  
94305

**Study participating centre**  
**Miriam Hospital**  
164 Summitt Avenue,  
Providence,  
Rhode Island  
United States of America  
2906

**Study participating centre**  
**Woodland Hills Medical Center**  
5601 De Soto Avenue, Woodland Hills, CA  
United States of America  
91365

**Study participating centre**  
**Ontario Medical Center**  
2295 S. Vineyard Avenue  
Ontario, CA  
United States of America  
91761

**Study participating centre**  
**San Diego Medical Center**  
9455 Clairemont Mesa Blvd  
San Diego, CA  
United States of America  
92123

**Study participating centre**  
**Zion Medical Center**  
4647 Zion Avenue, San Diego, CA  
United States of America  
92120

**Study participating centre**  
**Downey Medical Center**  
9333 Imperial Highway  
Downey, CA  
United States of America  
90241

**Study participating centre**  
**Riverside Medical Center**  
10800 Magnolia Avenue  
Riverside, CA  
United States of America  
92505

**Study participating centre**  
**Kaiser Permanente Los Angeles Medical Center**  
4867 West Sunset Boulevard, Los Angeles, California  
United States of America  
90027

**Study participating centre**  
**Orange County Anaheim Medical Center**  
3440 E. La. Palma Avenue  
Anaheim, CA  
United States of America  
92806

**Study participating centre**

**West Los Angeles Medical Center**

6041 Cadillac Avenue, Los Angeles, CA  
United States of America  
90034

**Study participating centre**

**Moreno Valley Medical Center**

27300 Iris Avenue  
Moreno Valley, CA  
United States of America  
92555

**Study participating centre**

**Fontana Medical Center**

9961 Sierra Avenue  
Fontana, CA  
United States of America  
92335

**Study participating centre**

**Panorama City Medical Center**

13651 Willard Street  
Panorama City, CA  
United States of America  
91402

**Study participating centre**

**South Bay Medical Center**

25825 S. Vermont Avenue  
Harbor City, CA  
United States of America  
90710

**Study participating centre**

**Duke University Medical Center**

2301 Erwin Road,  
Durham, North Carolina

United States of America  
27710

**Study participating centre**  
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1 Medical Center Drive,  
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United States of America  
3766

## Sponsor information

**Organisation**  
Gilead Sciences (United States)

**ROR**  
<https://ror.org/056546b03>

## Funder(s)

**Funder type**  
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**Funder Name**  
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**Alternative Name(s)**  
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**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
For-profit companies (industry)

**Location**  
United States of America

## Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Gilead Sciences shares anonymized individual patient data upon request or as required by law or regulation with qualified external researchers based on submitted curriculum vitae and reflecting non conflict of interest. The request proposal must also include a statistician. Approval of such requests is at Gilead Science's discretion and is dependent on the nature of the request, the merit of the research proposed, the availability of the data, and the intended use of the data. Data requests should be sent to [datarequest@gilead.com](mailto:datarequest@gilead.com) . Data will become available 18 months after study completion and will be accessible in a secured external environment. More information on Gilead's data sharing policy can be found here: <https://www.gilead.com/science-and-medicine/research/clinical-trials-transparency-and-data-sharing-policy>

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#"><u>Results article</u></a>	results	27/05/2020	29/10/2020	Yes	No
<a href="#"><u>Basic results</u></a>				No	No
<a href="#"><u>HRA research summary</u></a>			28/06/2023	No	No
<a href="#"><u>Participant information sheet</u></a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes