ISRCTN15874265 https://doi.org/10.1186/ISRCTN15874265

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

Submission date
29/10/2020

Recruitment status
No longer recruiting

Registration date
03/11/2020

Overall study status
Completed

Last Edited
19/03/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2020-000841-15

IRAS number
282007

ClinicalTrials.gov number
NCT04292899

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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)

Secondary outcome measures
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.

Overall study start date
11/02/2020

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 ≥ 18 years of age), or willing and able to provide assent (participants ≥12 and <18 years of age, where locally and nationally approved) prior to performing study procedures. For participants ≥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 ≥ 18 years (at all sites), or aged ≥12 and <18 years of age weighing ≥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 ≤4 days before randomization
4. Currently hospitalized
5. SpO2 ≤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

Age group
Other

Sex
Both

Target number of participants
6,000

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) ≥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 ≥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
England

France

Germany

Hong Kong

Italy

Japan

Korea, South

Netherlands

Scotland

Singapore

Spain

Sweden

Switzerland

Taiwan

United Kingdom

United States of America

Uruguay

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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
Dartmouth-Hitchcock Medical Center
1 Medical Center Drive,
Lebanon, New Hampshire
United States of America
3766

Sponsor information

Organisation
Gilead Sciences (United States)

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United States of America
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+1-833-445-3230
GileadClinicalTrials@gilead.com

Sponsor type
Industry

Website
http://www.gilead.com/

ROR
https://ror.org/056546b03

Funder(s)

Funder type
Industry

Funder Name
Gilead Sciences

Alternative Name(s)
Gilead, Gilead Sciences, Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

The Protocol is available at the following address within the supplemental materials: https://www.nejm.org/doi/full/10.1056/NEJMoa2015301

A redacted version of the latest protocol and statistical analysis plan, will be available on ClinicalTrials.gov when results are submitted: https://clinicaltrials.gov/ct2/show/NCT04292899

Intention to publish date
01/06/2021

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 . 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?
Basic results				No	No
Results article	results	27/05/2020	29/10/2020	Yes	No
HRA research summary			28/06/2023	No	No