ISRCTN85762140 https://doi.org/10.1186/ISRCTN85762140

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

Submission date
02/11/2020

Recruitment status
No longer recruiting

Registration date
03/11/2020

Overall study status
Completed

Last Edited
30/11/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[X] 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 moderate 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 was randomized and open-label (patients know what medication they are getting and for how long, doctors and study staff also know):
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, receiving RDV for 10 days or for not receiving RDV at all. In all treatment arms, participants still received standard of care treatment.

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 randomized to one of the following treatment groups:
1. Standard of care treatment together with RDV 200mg on Day 1 and then RDV 100mg on Days 2, 3, 4 and 5
2. Standard of care treatment together with RDV 200mg on Day 1 and then RDV 100mg on Days 2, 3, 4, 5, 6, 7, 8, 9 and 10
3. Standard of care treatment and no RDV

Part B Extension Treatment Group – For participants enrolled when Part A is completed, they received standard of care treatment together with RDV 200mg on Day 1 and then RDV 100mg on Days 2, 3, 4, 5, 6, 7, 8, 9, 10. The treatment may have been reduced to a total of 5 days based on the results from Part A.

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 133 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

EudraCT/CTIS number
2020-000842-32

IRAS number
282026

ClinicalTrials.gov number
NCT04292730

Secondary identifying numbers
GS-US-540-5774, IRAS 282026, CPMS 45459

Study information

Scientific 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

Study objectives
The odds of improvement for the RDV 5-day treatment group (Treatment Group 1) or 10-day treatment group (Treatment Group 2) is different from the odds of improvement for SOC treatment group (Treatment Group 3) with respect to clinical status assessed by a 7-point ordinal scale on Day 11.

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/0105

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 600 participants who met all eligibility criteria were randomized via an interactive web response system (IWRS) in 1:1:1 ratio into one of the following treatment groups:
Treatment Group 1: continued SOC therapy together with intravenous (IV) RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2, 3, 4, and 5
Treatment Group 2: continued SOC 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
Treatment Group 3: continued SOC therapy

Part B began enrollment after enrollment to Part A is complete. In Part B, an additional approximately 1,000 participants who met all of the eligibility criteria received:
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

Based on the results from Part A, or if treatment for 5 days is selected in a study of more severe disease, 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
(The ordinal scale is an assessment of the clinical status on a given day. Each day, the worst score from the previous day will be recorded. 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.)
The ordinal scale was recorded each day from Baseline until discharge or Day14, any change in category from Day 14 to discharge (or Day28) was also recorded.

Secondary outcome measures
Adverse Events were 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
26/06/2020

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 and requiring medical care for COVID-19
5. SpO2 >94% on room air 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
Mixed

Lower age limit
12 Years

Sex
Both

Target number of participants
1,600

Total final enrolment
1113

Key exclusion criteria
1. Participation in any other clinical trial of an experimental treatment for COVID-19
2. Concurrent treatment or planned concurrent treatment with other agents with actual or possible direct acting antiviral activity against SARS-CoV-2
3. Requiring mechanical ventilation at screening
4. ALT or AST >5 x ULN
Note: if per local practice only ALT is routinely measured, exclusion criteria will be evaluated on ALT alone
5. 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
6. Positive pregnancy test
7. Breastfeeding woman
8. Known hypersensitivity to the study drug, the metabolites, or formulation excipient

Date of first enrolment
15/03/2020

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

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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

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

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/NCT04292730)

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		15/09/2020	25/03/2021	Yes	No
Protocol (other)	V2.0	29/04/2020	30/11/2022	No	No
Statistical Analysis Plan	v1.0	26/06/2020	30/11/2022	No	No
HRA research summary			28/06/2023	No	No