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# Are anti-viral medications (remdesivir) a safe and feasible drug to improve outcomes for those living with Long COVID?

**Submission date**
26/03/2024

**Recruitment status**
No longer recruiting

**Registration date**
07/06/2024

**Overall study status**
Completed

**Last Edited**
08/10/2025

**Condition category**
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Following an infection with Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV2), one in ten people will experience persisting symptoms, or develop symptoms which can last for months and even years. These symptoms affect people in different ways and have been demonstrated to broadly impact physical, mental, and cognitive health. This is called Long COVID. Currently, there are no treatments available to address the issues that patients experience but anti-viral medications have been suggested as being potentially effective. The medication that will be used in this study is an existing anti-viral medication (remdesivir). In this study the researchers are specifically collecting information to understand how feasible this medication could be to help patients improve their condition and this will help to determine how likely this drug is able to be used within the wider Long COVID community.

Who can participate?
Patients aged 18 years and over with long COVID

What does the study involve?
Participants will undertake a series of tests to determine their symptoms and the impact that their condition has had on their bodily systems. The total duration of each participant's involvement is about 8 weeks, and this will involve 13 visits (15 visits if taking part in Exeter) at the closest study location (Derby or Exeter). Initial assessments are conducted over three separate visits and then all participants will be scheduled to receive five consecutive days of remdesivir. Following a period of 28 days, participants will be invited to repeat the same tests that were conducted before receiving the medication so that it can be determined how well the drug has worked.

What are the possible benefits and risks of participating?
If patients are able to tolerate the treatment and the research tasks the researchers will use this information to conduct a larger trial to determine how well this drug can be used to reduce the impact of Long COVID in a greater number of patients.
The use of remdesivir carries no higher risk to patients than when used in standard medical care.

In addition, there is an established safety profile for Remdesivir administered at 100 mg (preceded by a 200 mg loading dose) via intravenous infusion for up to 10 days, which exceeds the treatment duration outlined by the current study (5 days total). Therefore, the risk for the current treatment protocol can be considered low.
Hypersensitivity reactions including infusion-related and anaphylactic reactions have been observed during and following administration of remdesivir. Slower infusion rates, with a maximum infusion time of up to 120 minutes, can be considered to potentially prevent these signs and symptoms. Patients will be monitored for hypersensitivity reactions during and following administration of Remdesivir. Remdesivir will be discontinued if any occur and appropriate treatment is initiated. Participants will be screened to determine previous history of adverse reactions (ARs) to infusions/medicines during the initial screening process details of which will be shared with the study's clinical team to make the final decision about suitability to be recruited to the study. During the administration period, patients will be monitored by appropriate staff members and any ARs will be reported to the sponsor immediately and the appropriate documentation completed and shared with the appropriate study/ regulatory partners. Dosing and infusion rates have been discussed and agreed in line with the SmPC and the study's principal investigators who are medically trained and have clinical experience of using this IMP in acute settings.
Increased Transaminase elevations are listed as a common adverse event in the SmPC, therefore liver function will be tested prior to study enrolment and monitored at day 27 for safety purposes.
To negate any renal toxicity, all patients will have eGFR screened at the detailed screening visit and on Day 27 to determine suitability for participation.
There is a risk of reduced antiviral activity when co-administered with chloroquine or hydroxychloroquine. Patients who are taking either of these medications will be excluded from the study. We cannot guarantee participants will experience any benefits from taking part in this study as we do not know what the results will be, which is why we are carrying out this research. However, participation will contribute to the development of new knowledge and understanding of Long COVID and potential treatments, which could help improve the care of people with Long COVID in the future.
COVID-19 is a threat to these patients therefore mitigation of transmission at each site will be achieved by encouraging all participants and research staff in direct contact with participants to complete lateral flow tests in the event of experiencing COVID-19 symptoms. FFP3 masks will be provided at each site for all research/clinical staff and participants. Locally provided surgical masks may also be used. Where spaces do not have windows and adequate ventilation the use of a high-efficiency particulate absorbing(HEPA) filter is mandatory and will be provided by the study. All equipment and facilities should employ cleaning and sterilising procedures before and after each session using locally approved cleaning products. This also includes participants and research staff using hand sanitiser as they enter and leave designated research spaces.
There is a risk of post-exertional symptom exacerbation and post-exertional malaise following completion of the CPET protocol. It has been developed with rigorous testing and piloting and has demonstrated tolerability within Long COVID patients as part of a research project (IRAS ID: 313936). This study now completed (December 2023) and there has been only one reported adverse event (AE) in any data collection sites (two internationally, three nationally) and over 175 tests. The outcome of the AE was unrelated. To ensure safety a strict inclusion criterion will support recruitment to the study. This excludes participation from those determined (through screening) to be at serious risk of experiencing post-exertional malaise.
Patients with Long COVID are at risk of fatigue and severe exacerbation of their symptoms if too much physical, emotional and cognitive stress is exerted. The following actions are in place; parking adjacent to the testing and treatment rooms, wheelchairs available, minimum noise levels, reduced distractions, low-level lighting in testing and treatment rooms where possible, rest periods provided between periods of talking. Participants will be asked to complete a series

of questionnaires. To limit fatigue these will be provided 24 hours in advance. Additional consideration will also be given to patients with Postural Tachycardia Syndrome (PoTS). Symptoms include dizziness, heart palpitations, and shortness of breath. Mitigations include encouraging fluids, raising the head of the bed if the patient is lying down, and encouraging patients to get up slowly to stand and not stand too long.
Participants in Exeter will be asked to consent to have two PET/CT scans, pre and post treatment. These scans take approximately 75 minutes. Patients are not allowed to eat for 6 hours prior to the scan. This is 4 hours for people living with insulin-dependent diabetes. The actions above will be followed to mitigate fatigue and virus exposure.

Where is the study run from?
University of Derby (UK)

When is the study starting and how long is it expected to run for?
March 2024 to September 2025

Who is funding the study?
Gilead Sciences (USA)

Who is the main contact?
Prof. Mark Faghy, m.faghy@derby.ac.uk

# Contact information

### Type(s)
Principal investigator

### Contact name
Prof Mark Faghy

### Contact details
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+44 (0)1332 592109
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### Type(s)
Scientific

### Contact name
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### ORCID ID
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PL6 8BU
-
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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
1007101

### ClinicalTrials.gov (NCT)
NCT05911906

### Protocol serial number
ERASE-LC-1007101, IRAS 1007101

# Study information

### Scientific Title
An open-label, clinical feasibility study of the efficacy of remdesivir for Long-COVID

### Acronym
ERASE-LC

### Study objectives
Primary objectives:
To assess the feasibility of the use of Remdesivir in the treatment of patients with Long COVID:
1. To ascertain screening and recruitment rates (overall and by different recruitment pathways).
2. Retention and dropout rate (due to the treatment and/or trial demands, overall and by centre).
3. Adherence to treatment regimen (attendance to 5 days of IMP).
4. Completeness of study assessments (CPET, Bloods, PET/CT if in Exeter).
5. Completeness of all data collection activities including baseline and +28 days after treatment.
6. Acceptability of outcome measurements (measured by completion rates).

Secondary objectives:
1. To identify the most clinically relevant primary outcome for the definitive study including:
1.1. Quality of life, functional status and symptom burden.
1.2. Tolerance to physical stimulus: exercise tolerance and reduced post exertional symptom exacerbation following incremental exercise.
1.3. Physiological function, physical function, cognitive function, and emotional status and/or capacity.
1.4. Biomarker and inflammatory profiles.
1.5. Exeter patients only: Microvascular function: whole body FDG uptake using PET/CT methods.
2. To determine the clinical safety and tolerance parameters of the use of Remdesivir in the treatment of patients with Long Covid.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 20/05/2024, South Central – Oxford B REC (Health Research Authority, 2 Redman Place, Stratford , London, E20 1JQ, United Kingdom; +44 (0)207 104 8134, +44 (0)207 104 8386, +44 (0)207 104 8019; oxfordb.rec@hra.nhs.uk), ref: 24/SC/0118

## Study design
Open-label clinical feasibility study

## Primary study design
Interventional

## Study type(s)
Safety, Efficacy

## Health condition(s) or problem(s) studied
Post COVID-19 condition, post COVID syndrome and/or Long COVID

## Interventions
Five days of remdesivir delivered via intravenous infusion. 100 mg powder for concentrate for solution for infusion.
Administered outside of current licensing indication for the treatment of COVID-19 in the hospitalised patient.
Single loading dose of 200 mg via intravenous infusion over 60 minutes on day 1, then maintenance dose of 100 mg via intravenous infusion over 30 minutes once daily for 4 consecutive days. The total duration of treatment is 5 days.

## Intervention Type
Drug

## Phase
Phase IV

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

## Primary outcome(s)
Current primary outcome measures as of 17/03/2025:
Number of patients:
1. Rates of screening (overall and by centre) measured at the end of recruitment
2. Recruitment rate (number of patients consented as a proportion of those screened by the different recruitment pathways) measured at the end of recruitment
3. Retention and dropout rate (due to the treatment and/or trial demands, overall and by centre) measured at last patient last visit
4. Adherence to treatment regime (number of participants attending clinic appointments and completing each treatment session [Days 14-22])
5. Attendance and completeness of study assessments (CPET, bloods, PET/CT if in Exeter) on Days 7, 8, 44, 51, 52 (55 in Exeter)
6. Completeness of all data collection activities including baseline and +28 days after IMP

7. Completion of patient-reported outcome measurements (>60% completion) on Days 0, 7, 8, 44, 51, 52

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4. Adherence to treatment regime (number of participants attending clinic appointments and completing each treatment session [Days 14-22])
5. Attendance and completeness of study assessments (CPET, bloods, PET/CT if in Exeter) on Days 7, 8, 44, 51, 52 (52 in Exeter)
6. Completeness of all data collection activities including baseline and +28 days after IMP
7. Completion of patient-reported outcome measurements (>60% completion) on Days 0, 7, 8, 44, 51, 52

## Key secondary outcome(s))

Current secondary outcome measures as of 10/09/2025:

1. Quality of life measured using EQ-5D-5L* on Day 0 and +28 days after IMP
2. Functional status measured using the Post COVID Functional Status Scale (PCFS*; Impact on daily life subscale of the Symptom Burden Questionnaire for Long COVID) on Day 0 and +28 days after IMP
3. Symptom burden measured using the Symptom Burden Questionnaire for Long COVID (LC Symptom Burden)*, Modified DePaul Symptom Questionnaire - Post Exertional Malaise (DSQ-PEM), Fatigue Assessment Scale (FAS)*, Multidimensional Fatigue Impact Scale (MFIS)* on Day 0 and +28 days after IMP
4. Physical function measured using the Medical Research Council (MRC) Dyspnoea Scale* on Day 0 and +28 days after IMP
5. Cognitive function measured using the Perceived Deficit Questionnaire (PDQ-5)* on Day 0 and +28 days after IMP
6. Psychological assessment using Generalised Anxiety Disorder (GAD-7)* on Day 0 and +28 days after IMP
7. Biochemical/inflammatory markers*: G-CSF, GM-CSF, IFN-α, IFN-γ, IL-1β, IL-1RA, IL-2, IL-2R, IL-4, IL-5, IL-6, IL-7, IL-8, IL-10, IL-12, IL-13, IL-15, IL-17, TNF-α, Eotaxin, IP-10, MCP-1, MIG, MIP-1α, MIP-1β, RANTES, EGF, FGF-basic, HGF, VEGF.
8. Physiological function and/or capacity measured on Day 0 and +28 days after IMP:
8.1. Maximum inspiratory and expiratory mouth pressure (MIP and MEP)
8.2. Lung function
8.3. Blood pressure*
8.4. Oxygen saturation*
8.5. Breathing rate*
8.6. Resting heart rate
8.7. Temperature*
8.8. 6-minute walk test (6MWT, Borg 6-20 and SPO2)
9. Tolerance to physical stimulus using CPET on Days 7, 8, 51 and 52:
9.1. First ventilatory threshold (VT1)
9.2. Peak oxygen consumption (VO2peak)
9.3. End-tidal CO2
10. Symptom profiling and tracking on Day 0 to day 52 measured using:

10.1. Symptom Score Inventory
10.2. Heart rate variability
11. Clinical safety and tolerance parameters: Adverse Events (AEs)/Serious Adverse Events (SAEs) /Adverse Reactions (ARs)/Serious Adverse Reactions (SARs)/Suspected Unexpected Serious Adverse Reactions (SUSARs) from Consent to day 52 (55 if Exeter)
12. Microvascular function using PET/CT (Exeter only): standardised uptake volume (SUV) and Ki of 18FDG uptake observed during PET/CT scans on Days 11 and 55

Please note that those with an asterisk (*) are also repeated on the day of the CPET test Pre-Intervention (Days 7 & 8) and Post-Intervention (Days 51 & 52).

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5. Cognitive function measured using the Perceived Deficit Questionnaire (PDQ-5)* on Day 0 and +28 days after IMP
6. Psychological assessment using Generalised Anxiety Disorder (GAD-7)* on Day 0 and +28 days after IMP
7. Biochemical/inflammatory markers: full blood count*, eGFR*, LFT*, CRP*, d-dimers*, IL6*, IL16*, IL18*, PCT*, IFN-Y*, TNF-A*, VEGF-D*, HLA-DP*, and Vitamin D* on Day 0 and +28 days after IMP
8. Physiological function and/or capacity measured on Day 0 and +28 days after IMP:
8.1. Maximum inspiratory and expiratory mouth pressure (MIP and MEP)
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9. Tolerance to physical stimulus using CPET on Days 7, 8, 51 and 52:
9.1. First ventilatory threshold (VT1)
9.2. Respiratory compensation point (RCP)
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9.4. End-tidal CO2
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9.1. First ventilatory threshold (VT1)
9.2. Respiratory compensation point (RCP)
9.3. Peak oxygen consumption (VO2peak)
9.4. End-tidal CO2
10. Symptom profiling and tracking on Day 0 to day 52 / day 53 if Exeter (daily) measured using:
10.1. Symptom Score Inventory
10.2. Heart rate variability
11. Clinical safety and tolerance parameters: Adverse Events (AEs)/Serious Adverse Events (SAEs) /Adverse Reactions (ARs)/Serious Adverse Reactions (SARs)/Suspected Unexpected Serious Adverse Reactions (SUSARs) from Consent to day 52 (53 if Exeter)
12. Microvascular function using PET/CT (Exeter only): standardised uptake volume (SUV) and Ki of 18FDG uptake observed during PET/CT scans on Days 9 and 53

Please note that those with an asterisk (*) are also repeated on the day of the CPET test Pre-Intervention (Days 7 & 8) and Post-Intervention (Days 51 & 52).

### Completion date
17/09/2025

# Eligibility

### Key inclusion criteria
Current participant inclusion criteria as of 17/03/2025:
1. ≥18 years of age at the time of enrolment
2. Previously confirmed or suspected SARS-CoV-2 infection
3. Confirmed or suspected diagnosis of Long COVID by a Health Care Practitioner according to the definition* provided by the World Health Organisation for persistent symptoms following a confirmed SARS-CoV-2 infection
4. Willing and able to provide informed consent, complete the surveys, and complete all planned clinical assessments, and return for scheduled study visits
5. Evidence of persistent symptom profile relative to pre-COVID-19 status as derived from patient reported outcome measures
6. Lives within commutable distance of the relevant site, at discretion of local PI.

Previous participant inclusion criteria as of 25/09/2024 to 17/03/2025:
1. ≥18 years of age at the time of enrolment
2. Previously confirmed or suspected SARS-CoV-2 infection
3. Confirmed or suspected diagnosis of Long COVID by a Health Care Practitioner according to the definition* provided by the World Health Organisation for persistent symptoms following a confirmed SARS-CoV-2 infection
4. Willing and able to provide informed consent, complete the surveys, and complete all planned clinical assessments, and return for scheduled study visits
5. Evidence of persistent symptom profile relative to pre-COVID-19 status as derived from patient reported outcome measures

*The WHO defines Long COVID as the continuation or development of new symptoms 3 months after the initial SARS-CoV-2 infection, with these symptoms lasting for at least 2 months with no other explanation

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3. Confirmed or suspected diagnosis of Long COVID by a Health Care Practitioner according to the definition* provided by the World Health Organisation for persistent symptoms following a confirmed SARS-CoV-2 infection
4. Willing and able to provide informed consent, complete the surveys, and complete all planned clinical assessments, and return for scheduled study visits
5. Has the use of a smartphone
6. Evidence of persistent symptom profile relative to pre-COVID-19 status as derived from patient reported outcome measures

*The WHO defines Long COVID as the continuation or development of new symptoms 3 months after the initial SARS-CoV-2 infection, with these symptoms lasting for at least 2 months with no other explanation

### Participant type(s)

Patient

## Healthy volunteers allowed
No

## Age group
Adult

## Lower age limit
18 years

## Sex
All

## Total final enrolment
73

## Key exclusion criteria
1. Treatment history of remdesivir, molnupiravir, paxlovid and/or any other COVID-19 antiviral medication (<6 months)
2. A diagnosis of a compromised immune system or function from a healthcare professional
3. Currently engaged in a physical rehabilitation programme or intervention aimed to improve Long COVID symptom profile and/or functional status
4. Recognised as a 'severe risk' of experiencing post-exertional malaise following engagement in physical tasks. Determined using the De Paul symptom questionnaire
5. Lack of mental capacity to provide informed consent
6. Unable to understand verbal English/have a hearing impairment that prevents adequate communication*
7. Participation in another clinical drug trial within the last 6 months
8. Currently pregnant, breastfeeding or attempting to get pregnant (i.e., not using effective methods of contraception)
9. Currently taking medications known to have an interaction with Remdesivir (e.g., chloroquine phosphate or hydroxychloroquine) as defined by British National Formulary (BNF) information on the selection, prescribing, dispensing and administration of medicines: https://bnf.nice.org.uk/interactions/remdesivir/
10. History of adverse reactions to anti-viral medication and intravenous/infusions
11. History of hepatic or renal impairment (eGFR <30 ml/min and LFTs ALT > x5 ULN)
12. Exeter participants only: no recent/long-standing history of CT (within 3 months)/ongoing radiotherapy treatment. Risks of accumulative burden to be discussed as part of study involvement but it is at the discretion of participants.

*Note:
1. English comprehension: potential participants who are unable to understand verbal English will not be eligible for this study. This is due to the necessity of telephone contact which is a key aspect of this study and the unavailability of validated questionnaires other than English.
2. Hearing impairment: unfortunately, if the participant has a hearing impairment that prevents adequate communication on the telephone, they will not be able to take part in the study. This will be clearly stated in the participant information sheet.

## Date of first enrolment
08/10/2024

**Date of final enrolment**
14/07/2025

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**University of Derby (Testing Centre)**
Kedleston Road
Derby
United Kingdom
DE22 1GB

**Study participating centre**
**University Hospitals of Derby & Burton NHS Foundation Trust (Treatment Centre)**
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

**Study participating centre**
**University of Exeter / Royal Devon University Healthcare NHS Foundation Trust (Testing /Treatment Centre)**
Level 1
Bowmoor House
Royal Devon and Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

**Study participating centre**
**Derbyshire Community Healthcare Services (Participant Identification Centre)**
Ashgreen Learning Disability Centre
Ashgate Road
Ashgate
United Kingdom
S42 7JE

# Sponsor information

**Organisation**
University of Derby

**ROR**
https://ror.org/02yhrrk59

# Funder(s)

**Funder type**
Industry

**Funder Name**
Gilead Sciences

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

**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**
During the study, the PenCTU data team will have access to the trial dataset, including identifiable participant data. Other members of the CTU and the wider study team will have restricted access to pseudo-anonymised study data. Access to the dataset will be granted to the Sponsor and host institution on request, to permit study-related monitoring, audits and inspections. Access will be overseen by the CTU data manager and trial manager. Access to the final dataset will be provided to the trial statisticians for analysis. After the trial has been reported, the anonymised individual participant data that underlie the results will be available on request from the CI and Sponsor, along with supplementary files as required (e.g., data dictionaries, blank data collection forms, analysis code, etc). Data will be shared with (or access

to the data will be provided to) requestors whose proposed use of the data has been approved by the CI and Sponsor, under an appropriate data-sharing agreement. It will not be possible to identify participants personally from any information shared.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |