ISRCTN40580903 https://doi.org/10.1186/ISRCTN40580903

Which treatment could lessen the severity of a coronavirus infection when compared with usual care in an NHS setting?

Submission date
14/05/2020

Recruitment status
No longer recruiting

Registration date
15/05/2020

Overall study status
Completed

Last Edited
30/08/2022

Condition category
Respiratory

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

Plain English summary of protocol

Current plain English summary as of 01/07/2020:

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Admissions to hospital and intensive care units of patients with SARS-CoV-2 pneumonia are increasing rapidly. In the UK, the mortality amongst hospital admissions is around 5.2% with case rates doubling every 2-3 days. The death rate following Intensive Care Unit (ICU) admission is currently about 50%. There is currently no vaccine or proven effective treatments for COVID-19 infection.
As COVID-19 is a new illness, we are constantly learning more about how it affects the human body. We know that the COVID-19 virus affects a number of different cells in your body, including a type of blood cell called a macrophage (immune cell), and that it can cause the number of these cells to increase in your body. To fight an infection, your immune cells produce proteins called cytokines and chemokines. These proteins can cause inflammation and at high levels can lead to damage in the tissues and organs in your body. Researchers believe this is why some people with COVID-19 infection become very ill.
This trial plans to look at a number of different potential treatments for patients with COVID-19. A new, unlicensed drug called namilumab which has been tested in patients with arthritis and other inflammatory conditions may reduce inflammation in the body caused by the coronavirus. It is currently being given to patients with COVID-19 in a clinical trial in Italy. Namilumab is being provided free of charge by Izana Bioscience Limited for use in this trial.
A drug called infliximab (Remsima) which is widely used to treat arthritis and other conditions may reduce inflammation in the body caused by the coronavirus. Infliximab is being provided free of charge by Celltrion Healthcare UK Limited for use in this trial.
A drug called Mylotarg is routinely used to treat a certain type of blood cancer and could be used to reduce the increased levels of inflammatory cells inside the body. NOTE: This treatment arm is not currently open to recruitment.
Once this inflammation has been reduced, it may be possible that the immune system will adapt and fight off the virus more effectively. If this treatment benefits people with COVID-19 in this trial, the drug will be included in another larger-scale clinical trial being conducted throughout

the UK, which is designed to compare treatments to find out which is the best at treating this infection.

Who can participate?
Hospitalised adult patients with a laboratory-confirmed diagnosis of COVID-19

What does the study involve?
In this trial, participants will be randomly allocated to receive either usual care only, or usual care and an active treatment. As well as the usual care group, there are currently three active treatment groups; Mylotarg, namilumab and infliximab. NOTE: The Mylotarg group is not open to recruitment at present. Namilumab and infliximab will be given through a drip into a vein in the participant's arm as a single dose on Day 1 of the trial. Participants will be actively monitored for 28 days as a part of the trial in addition to the standard medical treatment that they will receive.

What are the possible benefits and risks of participating?
If the patient is allocated to receive usual care only, the patient will receive the same medical care as all other patients being treated for COVID-19, this is known as the 'usual care' arm of the trial and carries no additional risks.
If the patient is allocated to receive usual care and an active treatment in the trial (known as the 'usual care' group) they will receive the treatment in addition to the usual medical care received by patients who have COVID-19. Patients may have side effects from the treatment whilst taking part in the trial. The trial is testing new ways of treating COVID-19. Although the drug being tested, Mylotarg, is used routinely in the treatment of a type of blood cancer, where there is a lot known about the side effects, it has not been used in the treatment of patients with COVID-19. It is possible that the side effects may be different when used to treat this disease. Everyone taking part in the trial will be monitored carefully for side effects. However, the doctors don't know all the side effects that may occur.
Mylotarg, namilumab and infliximab have not been used to treat patients with respiratory conditions before and we don't know how it will interact with the other drugs being used to treat COVID-19.
Namilumab is currently being used on compassionate grounds for COVID-19 patients in Italy, however this is still an unlicensed drug and more information is needed.
Side effects of any of the trial drugs may be mild or serious or may even be life-threatening.
T he first patients to receive Mylotarg treatment in this trial will be patients who are being treated in the ICU as they can be monitored very closely for any side effects during and after the infusion. Patients recruited to namilumab and infliximab arms can be recruited from and treated on the ward. The doctors may give participants medicines to help lessen side effects or the trial treatment may be postponed or stopped, depending on the side effects they experience.

Where is the study run from?
University Hospitals Birmingham NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2020 to May 2021

Who is funding the study?
UK Research and Innovation (UK)

Who is the main contact?
Dr Anna Rowe
catalyst@trials.bham.ac.uk

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Previous plain English summary as of 30/06/2020:

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Admissions to hospital and intensive care units of patients with SARS-CoV-2 pneumonia are increasing rapidly. In the UK, the mortality amongst hospital admissions is around 5.2% with case rates doubling every 2-3 days. The death rate following Intensive Care Unit (ICU) admission is currently about 50%. There is currently no vaccine or proven effective treatments for COVID-19 infection.
As COVID-19 is a new illness, we are constantly learning more about how it affects the human body. We know that the COVID-19 virus affects a number of different cells in your body, including a type of blood cell called a macrophage (immune cell), and that it can cause the number of these cells to increase in your body. To fight an infection, your immune cells produce proteins called cytokines and chemokines. These proteins can cause inflammation and at high levels can lead to damage in the tissues and organs in your body. Researchers believe this is why some people with COVID-19 infection become very ill.
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A drug called Mylotarg is routinely used to treat a certain type of blood cancer and could be used to reduce the increased levels of inflammatory cells inside the body. NOTE: This treatment arm is not currently open to recruitment.
Once this inflammation has been reduced, it may be possible that the immune system will adapt and fight off the virus more effectively. If this treatment benefits people with COVID-19 in this trial, the drug will be included in another larger-scale clinical trial being conducted throughout the UK, which is designed to compare treatments to find out which is the best at treating this infection.

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If the patient is allocated to receive usual care only, the patient will receive the same medical care as all other patients being treated for COVID-19, this is known as the 'usual care' arm of the trial and carries no additional risks.

If the patient is allocated to receive usual care and an active treatment in the trial (known as the 'usual care' group) they will receive the treatment in addition to the usual medical care received by patients who have COVID-19. Patients may have side effects from the treatment whilst taking part in the trial. The trial is testing new ways of treating COVID-19. Although the drug being tested, Mylotarg, is used routinely in the treatment of a type of blood cancer, where there is a lot known about the side effects, it has not been used in the treatment of patients with COVID-19. It is possible that the side effects may be different when used to treat this disease. Everyone taking part in the trial will be monitored carefully for side effects. However, the doctors don't know all the side effects that may occur.
Mylotarg, namilumab and infliximab have not been used to treat patients with respiratory conditions before and we don't know how it will interact with the other drugs being used to treat COVID-19. Side effects may be mild or serious or may even be life-threatening. The first patients to receive treatment in this trial will be patients who are being treated in the ICU as they can be monitored very closely for any side effects during and after the infusion. The doctors may give participants medicines to help lessen side effects or the trial treatment may be postponed or stopped, depending on the side effects they experience.

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March 2020 to May 2021

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Dr Anna Rowe
catalyst@trials.bham.ac.uk

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This trial plans to look at a number of different potential treatments for patients with COVID-19. The first treatment that will be looked at is called Mylotarg. This drug is routinely used to treat a

certain type of blood cancer and could be used to reduce the increased levels of inflammatory cells inside the body. Once this inflammation has been reduced, it may be possible that the immune system will adapt and fight off the virus more effectively.

If this treatment benefits people with COVID-19 in this trial, the drug will be included in another larger-scale clinical trial being conducted throughout the UK, which is designed to compare treatments to find out which is the best at treating this infection.

Who can participate?
Hospitalized adult patients with a laboratory-confirmed diagnosis of COVID-19

What does the study involve?
In this trial, participants will be randomly allocated to receive either usual care only, or usual care and an active treatment. The first treatment will be looked at is called Mylotarg, which will be given through a drip into a vein in the participant's arm on up to three separate occasions: on Day 1, Day 5, and Day 10 of the trial. The participant may not receive all three doses if they have recovered or they develop side effects and their trial doctor decides that they should not have further doses. Participants will be actively monitored for 28 days as a part of the trial in addition to the standard medical treatment that they will receive.

What are the possible benefits and risks of participating?
If the patient is allocated to receive usual care only, the patient will receive the same medical care as all other patients being treated for COVID-19, this is known as the 'usual care' arm of the trial and carries no additional risks.

If the patient is allocated to receive usual care and an active treatment in the trial (known as the 'usual care' arm of the trial) they will receive the treatment in addition to the usual medical care received by patients who have COVID-19. Patients may have side effects from the treatment whilst taking part in the trial. The trial is testing new ways of treating COVID-19. Although the drug being tested, Mylotarg, is used routinely in the treatment of a type of blood cancer, where there is a lot known about the side effects, it has not been used in the treatment of patients with COVID-19. It is possible that the side effects may be different when used to treat this disease. Everyone taking part in the trial will be monitored carefully for side effects. However, the doctors don't know all the side effects that may occur.

Mylotarg has not been used to treat patients with respiratory conditions before and we don't know how it will interact with the other drugs being used to treat COVID-19. Side effects may be mild or serious or may even be life-threatening. The first patients to receive Mylotarg in this trial will be patients who are being treated in the ICU – as we can monitor them very closely for any side effects during and after the infusion. Your doctors may give you medicines to help lessen side effects or the trial treatment may be postponed or stopped, depending on the side-effects you may experience.

Where is the study run from?
University Hospitals Birmingham NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
From March 2020 to May 2021

Who is funding the study?
UK Research and Innovation (UK)

Who is the main contact?
Dr Anna Rowe, catalyst@trials.bham.ac.uk

Study website
https://www.birmingham.ac.uk/research/crctu/trials/catalyst/index.aspx

Contact information

Type(s)
Public

Contact name
Dr Anna Rowe

Contact details
Cancer Research UK Clinical Trials Unit,
University of Birmingham
Birmingham
United Kingdom
B15 2TT
-
catalyst@trials.bham.ac.uk

Additional identifiers

EudraCT/CTIS number
2020-001684-85

IRAS number
282431

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RG_20-030, CPMS 45648, IRAS 282431

Study information

Scientific Title
A randomised phase II proof of principle multi-arm multi-stage trial designed to guide the selection of interventions for phase III trials in hospitalised patients with COVID-19 infection.

Acronym
CATALYST

Study objectives
To investigate potential agents in an early phase trial setting that elicit a change in the ration of oxygen saturation to fractional inspired oxygen concentration in COVID-19 patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/05/2020, East Midlands – Nottingham 2 (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8035 or +44 (0)207 104 8103; nottingham2.rec@hra.nhs.uk), ref: 20/EM/0115

Study design
Open-label phase II multi-arm multi-stage randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format.

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection) in hospitalised patients

Interventions
Current interventions as of 01/07/2020:

Randomisation will be performed according to a 1:1 ratio (Usual Care/Control Arm vs. Research Arms). Patients will be randomised using an online randomisation system, using stratification (variable of care status, either on ward or ICU) via minimisation, where relevant to the research arms.

Initial approval was received for a single centre trial, but an amendment is underway to make this a multi-centre trial.

Patients will be randomised into either a control group, or to receive an interventional treatment.
Arm 1: Usual Care (Control)
Arm 2: Usual Care + Gemtuzumab Ozogamicin - THIS ARMS IS NOT CURRENTLY OPEN TO RECRUITMENT
Arm 3: Usual Care + Namilumab
Arm 4: Usual Care + Infliximab

Arm 2: Gemtuzumab Ozogamicin will be given intravenously into the arm on up to three separate occasions: on Day 1, Day 5 and Day 10 of the trial. The patient may not receive all three doses if they have recovered or they develop side effects and their trial doctor decides that they

should not have any more. Participants will be actively followed up for 28 days from the last dose. - THIS
ARM IS NOT CURRENTLY OPEN TO RECRUITMENT

Arm 3: Namilumab will be given will be given intravenously into the arm on Day 1. Participants will be actively followed up for 28 days from the last dose.

Arm 4: Infliximab will be given will be given intravenously into the arm on Day 1. Participants will be actively followed up for 28 days from the last dose.

Please Note: Additional intervention arms will be added during the trial via substantial amendment to the protocol

Previous interventions:

Randomisation will be performed according to a 1:1 ratio (Usual Care/Control Arm vs. Research Arms). Patients will be randomised using an online randomisation system, using stratification (variable of care status, either on ward or ICU) via minimisation, where relevant to the research arms.

Initial approval was received for a single centre trial, but an amendment is underway to make this a multi-centre trial.

Patients will be randomised into either a control group, or to receive an interventional treatment.
Arm 1: Usual Care (Control)
Arm 2: Usual Care + Gemtuzumab Ozogamicin

Gemtuzumab Ozogamicin will be given intravenously into the arm on up to three separate occasions: on Day 1, Day 5 and Day 10 of the trial. The patient may not receive all three doses if they have recovered or they develop side effects and their trial doctor decides that they should not have any more. Participants will be actively followed up for 28 days from the first dose.

Please Note: Additional intervention arms will be added during the trial via substantial amendment to the protocol

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Gemtuzumab ozogamicin (Mylotarg), Namilumab, Infliximab (Remsima)

Primary outcome measure
Current primary outcome measure approved from 12/10/2020, updated 27/08/2021:
C-reactive protein levels measured by routine laboratory measurement from baseline and throughout a patients time on the trial (Day 1 through to a maximum of Day 28)

Previous primary outcome measure:
The ratio of the oxygen saturation to fractional inspired oxygen concentration (SpO2/FiO2),

calculated using SpO2 and FiO2 (or inspired oxygen) measurements taken as part of routine clinical care at least 4-hourly in intensive care, and 4- to 6-hourly on the wards for patients receiving active management. The ratio will be derived from these data from the electronic patient record from baseline (randomisation) to day 14, hospital discharge or death

Secondary outcome measures

Current secondary outcome measures approved from 12/10/2020, updated 27/08/2021:
These will be aligned with COMET core outcome set initiatives and assessed from baseline up to a maximum of Day 28:
1. Efficacy measured by:
1.1 WHO R&D Blueprint Group Clinical Progression improvement Scale (1-10 scale; for the purposes of this trial level 0, no viral RNA detected, will not be assessed).
2. Patient status measured by:
2.1. The ratio of the oxygen saturation to fractional inspired oxygen concentration (SpO2/FiO2), calculated using SpO2 and FiO2 (or inspired oxygen) measurements taken as part of routine clinical care at least 4-hourly in intensive care, and 4- to 6-hourly on the wards for patients receiving active management. The ratio will be derived from these data from the electronic patient record
2.2 Respiratory rate taken as part of routine clinical care 4-6 hourly
2.3. Body temperature taken as part of routine clinical care at 4-6 hourly
2.4. Length of hospital stay from the electronic patient record at hospital discharge or death
2.5. Hospital survival status at Day 28 or number of hospital free days
2.6. Proportion of patients discharged at Day 28
2.6. Destination of discharge from the electronic patient record at hospital discharge or death
3. Routine laboratory measurement (from baseline up to a maximum of Day 28) of:
3.1 C-reactive protein (CRP)
3.2 Lymphocyte count, neutrophil count
3.3 Neutrophil:lymphocyte ratios
3.4 Ferritin, D-dimer and LDH
4. Safety measured by:
4.1. Adverse events (AEs) as recorded by Common Terminology Criteria for Adverse Events (CTCAE), version 4.03 (Appendix 1) of grade ≥3 with interest in veno-occlusive disease, secondary infection and allergic reaction in the event of an AE
4.2. Overall survival

Previous secondary outcome measures:
These will be aligned with COMET core outcome set initiatives.
1. Efficacy measured by:
1.1. Time to improvement at randomisation to day 7, 14 and 28. Improvement is defined as at least a two-point improvement on the WHO R&D Blueprint Group Clinical Progression improvement Scale (1-10 scale; for the purposes of this trial level 0, no viral RNA detected, will not be assessed).
1.2. WHO R&D Blueprint Group Clinical Progression Scale at randomisation to day 7, 14 and 28.
2. Patient status measured by:
2.1. Respiratory rate taken as part of routine clinical care 4-6 hourly from baseline (randomisation) to day 14, hospital discharge or death
2.2. Body temperature taken as part of routine clinical care at 4-6 hourly from baseline (randomisation) to day 14, hospital discharge or death
2.3. Length of hospital stay from the electronic patient record at hospital discharge or death
2.4. Hospital survival status at day 28
2.5. Proportion of patients discharged at day 28

2.6. Destination of discharge from the electronic patient record at hospital discharge or death
2.7. Routine laboratory measurement of C-reactive protein (CRP), Full blood count with neutrophil:lymphocyte ratios, Ferritin, D-Dimer, LDH and triglycerides at baseline, 1, 3, 7 and 14 days.
3. Safety measured by:
3.1. Adverse events (AEs) as recorded by Common Terminology Criteria for Adverse Events (CTCAE), version 4.03 (Appendix 1) of grade ≥3 with interest in veno-occlusive disease, secondary infection and allergic reaction in the event of an AE
3.2. Survival status at day 28, hospital discharge or death

Overall study start date
26/03/2020

Completion date
01/05/2021

Eligibility

Key inclusion criteria
Current inclusion criteria approved from 12/10/2020, updated 27/08/2021:
1. Hospitalised adult (≥16 yrs) patients with a clinical picture strongly suggestive of SARS-CoV-2 pneumonia (confirmed by chest X-ray or CT scan, with or without a positive reverse transcription polymerase chain reaction [RT-PCR] assay)
2. CRP ≥40 mg/l
Arm 2: (Usual Care + Gemtuzumab Ozogamicin) Specific Inclusion Criteria (NB. THIS ARM IS NOT RECRUITING AT THIS TIME)
The following criterion will apply until at least three patients have been allocated the IMP: intubated and requiring mechanical ventilation

Previous inclusion criteria from 01/07/2020:
1. Hospitalised adult (≥16 yrs) patients with a clinical picture strongly suggestive of SARS-CoV-2 pneumonia (confirmed by chest X-ray or CT scan, with or without a positive reverse transcription polymerase chain reaction [RT-PCR] assay)
2. Oxygen saturation (SaO2) of ≤94% while breathing ambient air or a ratio of the partial pressure of Oxygen (PaO2) to the fraction of inspired oxygen (FiO2) (PaO2:FiO2) ≤ 300 mg Hg (≤40kPa)
Arm 2: (Usual Care + Gemtuzumab Ozogamicin) Specific Inclusion Criteria (NB. THIS ARM IS NOT RECRUITING AT THIS TIME)
The following criterion will apply until at least 3 patients have been allocated the IMP: intubated and requiring mechanical ventilation

Original inclusion criteria:
1. Hospitalized patients with a laboratory-confirmed diagnosis of SARS-CoV-2 pneumonia (confirmed by reverse transcription polymerase chain reaction [RT-PCR] assay and chest X-ray)
2. Aged ≥16 years
3. Oxygen saturation (SaO2) of ≤94% while breathing ambient air or a ratio of the partial pressure of Oxygen (PaO2) to the fraction of inspired oxygen (FiO2) (PaO2:FiO2) ≤300 mgHg (≤40kPa)
4. Participants recruited up until 3 patients are included in Arm 2 (usual care + gemtuzumab ozogamicin) must be intubated and requiring mechanical ventilation

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
This is a platform trial, and is anticipated to have up to 14 interventional arms. These will all open at different times, and arms may close following an interim analysis before reaching the recruitment target of 42 patients per arm.

Total final enrolment
146

Key exclusion criteria
Current exclusion criteria approved from 12/10/2020, updated 27/08/2021:
1. Patient or legal representative refusal
2. Receiving palliative care with no active treatment
3. Current participation in another COVID-19 interventional trial. Co-enrolment into RECOVERY-RS is allowed
4. Known pregnancy or breastfeeding women
5. Women of child bearing potential who are unwilling to use effective contraception (i.e. barrier, oral contraceptive pill, implanted contraception, or previous hysterectomy, bilateral oophorectomy) for the duration of the trial and the maximum period specified in Table 2.
6. Non-vasectomised men, sexually active with women of childbearing potential, who are not willing to practise effective contraception (i.e. condom with spermicide) for the duration of the trial and the maximum period specified in Table 2.
7. Known HIV or chronic Hepatitis B or C infection
8. Known contraindications to any of the Investigational Medicinal Products (IMPs)
9. Concurrent immunosuppression with biological agents
10. History of haematopoietic stem cell transplant or solid organ transplant
11. Known hypersensitivity to drug products or excipients
12. Patients with tuberculosis or other severe infections such as (non-COVID-19) sepsis, abscesses, and opportunistic infections requiring treatment
13. Patients with moderate or severe heart failure (NYHA class III/IV)
14. Any other indication or medical history, that in the opinion of the local investigator means the patient is unsuitable for trial participation

Previous exclusion criteria from 01/07/2020:
1. Patient or legal representative refusal
2. Receiving palliative care with no active treatment
3. Known veno-occlusive disease
4. Chronic Obstructive Pulmonary Disease (known FEV1 < 50% predicted or ambulatory or long term oxygen therapy)
5. Neutrophil count < 2 x 109/l or White Blood Cell Count < 4.0 x 109/l
6. Current participation in another COVID-19 interventional trial. Co-enrolment into
7. RECOVERY-RS is allowed
8. Known pregnancy or breastfeeding women

9. Women of child bearing potential who are unwilling to use effective contraception (i.e. barrier, oral contraceptive pill, implanted contraception, or previous hysterectomy, bilateral oophorectomy) for the duration of the trial and the maximum period specified below.
10. Non-vasectomised men, sexually active with women of child bearing potential, who are not willing to practise effective contraception (i.e. condom with spermicide) for the duration of the trial and the maximum period specified below.
11. Known HIV or chronic Hepatitis B or C infection
12. Known contraindications to any of the Investigational Medicinal Products (IMPs)
13. Concurrent immunosuppression with biological agents
14. History of haematopoietic stem cell transplant or solid organ transplant
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16. Patients with tuberculosis or other severe infections such as (non-COVID-19) sepsis, abscesses, and opportunistic infections requiring treatment
17. Patients with moderate or severe heart failure (NYHA class III/IV)
18. Any other indication or medical history, that in the opinion of the local investigator means the patient is unsuitable for trial participation

Duration of Effective Contraception (after last dose IMP)

Arm 2: Gemtuzumab Ozogamicin
FEMALES - 7 months (must use 2 effective forms of contraception) *
MALES - 4 months

Arm 3: Namilumab
FEMALES and MALES 18 weeks after the last administration of namilumab

Arm 4: - Infliximab
FEMALES and MALES 26 weeks after the last administration of Infliximab

* If using hormonal agents the same method must have been used for at least 1 month before the trial dosing and patients must use a barrier method during that time period

Original exclusion criteria:
1. Patient or legal representative refusal
2. Receiving palliative care with no active treatment
3. Known veno-occlusive disease
4. Chronic Obstructive Pulmonary Disease (known FEV1 <50% predicted or ambulatory or long term oxygen therapy)
5. Neutrophil count <2 $x10^9$ /l or White Blood Cell Count <4.0 $x10^9$ /l
6. Current participation in another COVID-19 interventional trial
7. Pregnancy or breastfeeding
8. Women of childbearing potential who are unwilling to use two forms of effective contraception (i.e. barrier, oral contraceptive pill, implanted contraception, or previous hysterectomy, bilateral oophorectomy) for the duration of the trial and up to 7 months after the trial drug is administered. If using hormonal agents the same method must have been used for at least one month before the trial dosing and patients must use a barrier method during that time period.
9. Non-vasectomised men, sexually active with women of childbearing potential, who are not willing to practise effective contraception (i.e. condom with spermicide) for the duration of the trial and up to 4 months after the trial drug is administered
10. Known HIV or chronic Hepatitis B or C infection
11. Known contraindications to any of the Investigational Medicinal Products (IMPs)

12. Concurrent immunosuppression with biological agents or prednisone dose >20mg
13. History of hematopoietic stem cell transplant or solid organ transplant
14. Any other indication or medical history, that in the opinion of the local investigator means the patient is unsuitable for trial participation

Date of first enrolment
16/05/2020

Date of final enrolment
30/11/2020

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
South Wharf Road
St Mary's Hospital
London
United Kingdom
W2 1NY

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Royal Bolton Hospital
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre
University of Hospital of Wales, Cardiff
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
University College London Hospital
12 Queen Square
London
United Kingdom
WC1N 3BG

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Swansea
United Kingdom
SA6 6NL

Study participating centre
The Royal Hallamshire Hospital
Glossop Road
Sheffield
United Kingdom
S10 2JF

Sponsor information

Organisation
University of Birmingham

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT
-
researchgovernance@contacts.bham.ac.uk

Sponsor type
University/education

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Research organisation

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

A Lay Summary of the findings will be produced after the completion of all analysis and made available to all patients via trial websites. The Lay Summary will be produced by the Sponsor and reviewed by a PPI panel. At the end of the trial, the findings will be published in peer-reviewed medical and scientific journals. These publications will be available upon request from the patient's trial doctor.

Results will also be disseminated at internal meetings, conferences, trial web site and peer-reviewed scientific journals.

Intention to publish date
31/05/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (preprint)	non-peer-reviewed protocol in preprint	12/02/2021	23/03/2021	No	No
Preprint results	non-peer-reviewed results in preprint	09/06/2021	11/06/2021	No	No
Results article		16/12/2021	20/12/2021	Yes	No
Protocol article		11/11/2021	30/08/2022	Yes	No
HRA research summary			28/06/2023	No	No