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Otilimab in patients with severe coronavirus-related lung disease

Submission date
20/07/2020

Recruitment status
No longer recruiting

Registration date
28/07/2020

Overall study status
Completed

Last Edited
16/06/2022

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
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. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.
In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of April 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.
Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.
Patients infected with SARS-CoV-2 can develop severe lung complications that require as a minimum oxygen treatment in hospital. This study will test a type of medicine that is a monoclonal antibody called otilimab. Normally, the body's immune system makes antibodies that attack bacteria and viruses, helping to fight infection. Monoclonal antibodies are made in a laboratory and have been purposefully designed to work as medicines by targeting specific cells or substances in the body. Otilimab blocks a specific chemical messenger called granulocyte-macrophage colony-stimulating factor (GM-CSF) which is involved in inflammation. Higher levels of GM-CSF are found in the blood and lungs of patients with severe pulmonary COVID-19 related disease. It is thought that blocking GM-CSF will improve lung function, improve clinical status, and improve the chances of survival. The aim of this study is to test how well otilimab works in COVID-19 patients who have developed severe lung complications compared to placebo, both with the best standard of care.

Who can participate?
Hospitalized participants with new-onset hypoxia (tissues of the body are starved of oxygen) requiring significant oxygen support or requiring mechanical ventilation.

What does the study involve?
Each participant will be randomly allocated to receive a single dose of otilimab or placebo (dummy drug) given as an infusion (IV) in addition to standard of care. A placebo is a medicine that looks like the study medicine but doesn't contain any active medication. There is a 50% chance of receiving either otilimab or placebo chosen randomly by a computer. The participant, site staff or GSK will not know which treatment they had until after the study has finished. There will be a screening period, IV dosing at Day 1, daily clinical and safety assessments until discharge or Day 28, whichever is sooner, regular blood tests, and follow up at Days 42 and 60. During the study, participants may require a chest x-ray. There will be no further treatment available with otilimab at the end of the study.

What are the possible benefits and risks of participating?
There may be no perceived benefit to the participant other than the increased monitoring of the participants' disease. Information from this study will help doctors and scientists to learn more about COVID-19-related respiratory disease and its treatment. This information may help future patients with COVID 19 respiratory-related disease. Otilimab has been given to just over 400 people in completed clinical studies. These studies have involved healthy volunteers and patients with rheumatoid arthritis or multiple sclerosis. Otilimab is currently being investigated in patients with rheumatoid arthritis in ongoing clinical studies. More than 700 patients in total have been enrolled to date. To date most people have tolerated otilimab well but there are some potential risks. Since otilimab works on the cells in the immune system, participants may be at risk of:
Cytokine release syndrome: Antibody drugs like otilimab can, in rare instances, trigger a widespread abnormal inflammation response within the body. This can potentially be life-threatening, and might cause additional symptoms: rash, headache, nausea, tiredness, vomiting, confusion, rigors low blood pressure, breathing difficulties, increased need for oxygen, muscle aches, worsening kidney function, worsening liver function, other laboratory test abnormal values, and multi-organ system failure that can be fatal. Based on our understanding of otilimab action this risk is thought to be very rare.
Allergic reaction: Antibody drugs like otilimab may cause allergic reactions, although in general, severe reactions happen very rarely.
Increased risk of infection: Otilimab acts on the immune system and may reduce the participant's resistance to infection. The participant may also be at increased risk of getting an infection (including lung infection). Infections have been reported in participants who received otilimab in clinical trials; however, the exact effect of otilimab on causing infections is not yet known.
Risk of changes in blood cell counts: Otilimab may reduce the number of certain types of blood cells (in particular neutrophils) and may make the participant more prone to infections.
Because otilimab reduces normal activity of GM-CSF in the lungs there is a risk of:
Lung disease: Pulmonary alveolar proteinosis (or PAP) is a very rare lung disease known to be caused by reduced levels of GM-CSF in the lungs. It is characterised by the build-up of grainy material in the alveoli (air sacs) of the lungs which makes it difficult for the lungs to absorb oxygen and over time leads to breathing difficulties. There is a risk that treatment with otilimab could result in the development of PAP; however, in this study this risk is considered very low because only a single dose of otilimab will be administered on day 1. To date, PAP has not been seen in any clinical studies with otilimab.
Delayed recovery to infection: GM-CSF has been noted to play a role in helping the lung fight infection and recover from any injury. Therefore, it is possible that otilimab, by blocking GM-CSF, may affect the ability of the lungs to fight lung infection or properly recover from infection
Other risks include:
Risk of cancer: otilimab may reduce the activity of the immune system. Medicines that affect the immune system may increase the risk of certain cancers. So far, an increased risk of cancer has

not been seen in any of the previous clinical or animal studies with otilimab.
Injection site reaction: As the study drug will be given through an IV cannula, there is a risk of developing local inflammation around the injection site. This could include redness, swelling and infection.

Where is the study run from?
GlaxoSmithKline (UK)

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

Who is funding the study?
GlaxoSmithKline (UK)

Who is the main contact?
Unfortunately, this study is not recruiting public volunteers at this time. This is because the research isn't ready for volunteers yet or the researchers are directly identifying volunteers in certain areas or hospitals. Please do not contact the research team as they will not be able to respond. For more information about COVID-19 research, visit the Be Part of Research homepage.

Contact information

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Public

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2020-001759-42

Integrated Research Application System (IRAS)
214094

ClinicalTrials.gov (NCT)
NCT04376684

Protocol serial number
CPMS 45580, IRAS 214094

Study information

Scientific Title
A randomised, double-blind, placebo-controlled, study evaluating the efficacy and safety of otilimab IV in patients with severe pulmonary COVID-19 related disease

Acronym
OSCAR

Study objectives
The aim of this study is to evaluate the benefit-risk of a single infusion of otilimab in the treatment of patients with severe pulmonary COVID-19 related disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/05/2020, Yorkshire & The Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8340; leedswest.rec@hra.nhs.uk), REC ref: 20/YH/0174

Study design
Multicentre randomized double-blind placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe pulmonary COVID-19 (SARS-CoV-2 infection) related disease

Interventions
This study is a multi-center, randomized, double-blind, placebo-controlled trial to assess the efficacy and safety of otilimab for the treatment of severe pulmonary COVID-19 related disease. The study population consists of hospitalized participants with new-onset hypoxia requiring significant oxygen support or requiring invasive mechanical ventilation (≤48 hours before dosing). All participants will receive standard of care as per institutional protocols, in addition to study treatment. Participants will be randomized 1:1 by interactive response technology (IRT) in a blinded manner to receive either a blinded 1-hour infusion of otilimab 90 mg or placebo IV in addition to standard of care. Participants will be assessed daily until discharge (or Day 28, whichever is sooner), and followed up at Days 42 and 60 after randomization.

Intervention Type
Biological/Vaccine

Phase
Phase II

Drug/device/biological/vaccine name(s)
Otilimab

Primary outcome(s)
Proportion of participants alive and free of respiratory failure at Day 28. Participants are alive and free of respiratory failure if they are in category 1, 2, 3 or 4 from the GlaxoSmithKline (GSK) modified version ordinal scale adapted from World Health Organization (WHO) scale 2020. The 8-point scale is as follows: 1) Non-hospitalized, no limitation of activity; 2) Non-hospitalized, limitation of activity; 3) Hospitalized, no oxygen therapy; 4) Hospitalized, low-flow oxygen by mask or nasal prongs; 5) Hospitalized, high-flow oxygen (≥15L/min), continuous positive airway pressure (CPAP), bilevel positive airway pressure (BIPAP), non-invasive ventilation; 6) Hospitalized, intubation and mechanical ventilation; 7) Hospitalized, mechanical ventilation plus additional organ support; 8) Death.

Key secondary outcome(s))
1. Number of deaths due to all causes at Day 60, taken from the medical records and as recorded in the eCRF
2. Time to number of deaths due to all causes at Day 60, taken from the medical records and as recorded in the eCRF
3. Proportion of participants alive and free of respiratory failure at Day 7. Participants alive and free of respiratory failure if they are in category 1, 2, 3 or 4 from the GlaxoSmithKline (GSK) modified version ordinal scale adapted from World Health Organization (WHO) scale 2020. The 8-point scale is as follows: 1) Non-hospitalized, no limitation of activity; 2) Non-hospitalized, limitation of activity; 3) Hospitalized, no oxygen therapy; 4) Hospitalized, low-flow oxygen by mask or nasal prongs; 5) Hospitalized, high-flow oxygen (≥15L/min), continuous positive airway pressure (CPAP), bilevel positive airway pressure (BIPAP), non-invasive ventilation; 6) Hospitalized, intubation and mechanical ventilation; 7) Hospitalized, mechanical ventilation plus additional organ support; 8) Death.
4. Proportion of participants alive and free of respiratory failure at Day 14. Participants are alive and free of respiratory failure if they are in category 1, 2, 3 or 4 from the GlaxoSmithKline (GSK) modified version ordinal scale adapted from World Health Organization (WHO) scale 2020. The 8-point scale is as follows: 1) Non-hospitalized, no limitation of activity; 2) Non-hospitalized, limitation of activity; 3) Hospitalized, no oxygen therapy; 4) Hospitalized, low-flow oxygen by

mask or nasal prongs; 5) Hospitalized, high-flow oxygen (≥15L/min), continuous positive airway pressure (CPAP), bilevel positive airway pressure (BIPAP), non-invasive ventilation; 6) Hospitalized, intubation and mechanical ventilation; 7) Hospitalized, mechanical ventilation plus additional organ support; 8) Death.
5. Proportion of participants alive and free of respiratory failure at Day 42. Participants are alive and free of respiratory failure if they are in category 1, 2, 3 or 4 from the GlaxoSmithKline (GSK) modified version ordinal scale adapted from World Health Organization (WHO) scale 2020. The 8-point scale is as follows: 1) Non-hospitalized, no limitation of activity; 2) Non-hospitalized, limitation of activity; 3) Hospitalized, no oxygen therapy; 4) Hospitalized, low-flow oxygen by mask or nasal prongs; 5) Hospitalized, high-flow oxygen (≥15L/min), continuous positive airway pressure (CPAP), bilevel positive airway pressure (BIPAP), non-invasive ventilation; 6) Hospitalized, intubation and mechanical ventilation; 7) Hospitalized, mechanical ventilation plus additional organ support; 8) Death.
6. Proportion of participants alive and free of respiratory failure at Day 60. Participants are alive and free of respiratory failure if they are in category 1, 2, 3 or 4 from the GlaxoSmithKline (GSK) modified version ordinal scale adapted from World Health Organization (WHO) scale 2020. The 8-point scale is as follows: 1) Non-hospitalized, no limitation of activity; 2) Non-hospitalized, limitation of activity; 3) Hospitalized, no oxygen therapy; 4) Hospitalized, low-flow oxygen by mask or nasal prongs; 5) Hospitalized, high-flow oxygen (≥15L/min), continuous positive airway pressure (CPAP), bilevel positive airway pressure (BIPAP), non-invasive ventilation; 6) Hospitalized, intubation and mechanical ventilation; 7) Hospitalized, mechanical ventilation plus additional organ support; 8) Death.
7. Time to recovery from respiratory failure. Time will be recorded from dosing to recovery from respiratory failure. Participants are in respiratory failure if they are in category 5 or above from the GlaxoSmithKline (GSK) modified version ordinal scale adapted from World Health Organization (WHO) scale 2020. The 8-point scale is as follows: 1) Non-hospitalized, no limitation of activity; 2) Non-hospitalized, limitation of activity; 3) Hospitalized, no oxygen therapy; 4) Hospitalized, low-flow oxygen by mask or nasal prongs; 5) Hospitalized, high-flow oxygen (≥15L /min), continuous positive airway pressure (CPAP), bilevel positive airway pressure (BIPAP), non-invasive ventilation; 6) Hospitalized, intubation and mechanical ventilation; 7) Hospitalized, mechanical ventilation plus additional organ support; 8) Death.
8. Proportion of participants alive and independent of supplementary oxygen at Day 7. Participants are independent of supplementary oxygen if they are in category 1, 2 or 3 from the GlaxoSmithKline (GSK) modified version ordinal scale adapted from World Health Organization (WHO) scale 2020. The 8-point scale is as follows: 1) Non-hospitalized, no limitation of activity; 2) Non-hospitalized, limitation of activity; 3) Hospitalized, no oxygen therapy; 4) Hospitalized, low-flow oxygen by mask or nasal prongs; 5) Hospitalized, high-flow oxygen (≥15L/min), continuous positive airway pressure (CPAP), bilevel positive airway pressure (BIPAP), non-invasive ventilation; 6) Hospitalized, intubation and mechanical ventilation; 7) Hospitalized, mechanical ventilation plus additional organ support; 8) Death.
9. Proportion of participants alive and independent of supplementary oxygen at Day 14. Participants are independent of supplementary oxygen if they are in category 1, 2 or 3 from the GlaxoSmithKline (GSK) modified version ordinal scale adapted from World Health Organization (WHO) scale 2020. The 8-point scale is as follows: 1) Non-hospitalized, no limitation of activity; 2) Non-hospitalized, limitation of activity; 3) Hospitalized, no oxygen therapy; 4) Hospitalized, low-flow oxygen by mask or nasal prongs; 5) Hospitalized, high-flow oxygen (≥15L/min), continuous positive airway pressure (CPAP), bilevel positive airway pressure (BIPAP), non-invasive ventilation; 6) Hospitalized, intubation and mechanical ventilation; 7) Hospitalized, mechanical ventilation plus additional organ support; 8) Death.
10. Proportion of participants alive and independent of supplementary oxygen at Day 28. Participants are independent of supplementary oxygen if they are in category 1, 2 or 3 from the GlaxoSmithKline (GSK) modified version ordinal scale adapted from World Health Organization

(WHO) scale 2020. The 8-point scale is as follows: 1) Non-hospitalized, no limitation of activity; 2) Non-hospitalized, limitation of activity; 3) Hospitalized, no oxygen therapy; 4) Hospitalized, low-flow oxygen by mask or nasal prongs; 5) Hospitalized, high-flow oxygen (≥15L/min), continuous positive airway pressure (CPAP), bilevel positive airway pressure (BIPAP), non-invasive ventilation; 6) Hospitalized, intubation and mechanical ventilation; 7) Hospitalized, mechanical ventilation plus additional organ support; 8) Death.
11. Proportion of participants alive and independent of supplementary oxygen at Day 42. Participants are independent of supplementary oxygen if they are in category 1, 2 or 3 from the GlaxoSmithKline (GSK) modified version ordinal scale adapted from World Health Organization (WHO) scale 2020. The 8-point scale is as follows: 1) Non-hospitalized, no limitation of activity; 2) Non-hospitalized, limitation of activity; 3) Hospitalized, no oxygen therapy; 4) Hospitalized, low-flow oxygen by mask or nasal prongs; 5) Hospitalized, high-flow oxygen (≥15L/min), continuous positive airway pressure (CPAP), bilevel positive airway pressure (BIPAP), non-invasive ventilation; 6) Hospitalized, intubation and mechanical ventilation; 7) Hospitalized, mechanical ventilation plus additional organ support; 8) Death.
12. Proportion of participants alive and independent of supplementary oxygen at Day 60. Participants are independent of supplementary oxygen if they are in category 1, 2 or 3 from the GlaxoSmithKline (GSK) modified version ordinal scale adapted from World Health Organization (WHO) scale 2020. The 8-point scale is as follows: 1) Non-hospitalized, no limitation of activity; 2) Non-hospitalized, limitation of activity; 3) Hospitalized, no oxygen therapy; 4) Hospitalized, low-flow oxygen by mask or nasal prongs; 5) Hospitalized, high-flow oxygen (≥15L/min), continuous positive airway pressure (CPAP), bilevel positive airway pressure (BIPAP), non-invasive ventilation; 6) Hospitalized, intubation and mechanical ventilation; 7) Hospitalized, mechanical ventilation plus additional organ support; 8) Death.
13. Time to last dependence on supplementary oxygen [Time Frame: Day 28]. Time will be recorded from dosing to last dependence on supplementary oxygen. Participants are dependent on supplementary oxygen if they are in category 4 or above from the GlaxoSmithKline (GSK) modified version ordinal scale adapted from World Health Organization (WHO) scale 2020. The 8-point scale is as follows: 1) Non-hospitalized, no limitation of activity; 2) Non-hospitalized, limitation of activity; 3) Hospitalized, no oxygen therapy; 4) Hospitalized, low-flow oxygen by mask or nasal prongs; 5) Hospitalized, high-flow oxygen (≥15 l/min), continuous positive airway pressure (CPAP), bilevel positive airway pressure (BIPAP), non-invasive ventilation; 6) Hospitalized, intubation and mechanical ventilation; 7) Hospitalized, mechanical ventilation plus additional organ support; 8) Death.
14. Proportion of participants admitted to Intensive Care Unit (ICU), taken from the medical records and as recorded in the eCRF. For participants not in ICU at time of dosing, the proportion of participants admitted to the ICU prior to Day 28.
15. Time to final Intensive Care Unit (ICU) discharge, taken from the medical records and as recorded in the eCRF [Time Frame: Day 28]. Defined as the time from dosing to when the participant is discharged from the ICU.
16. Time to final hospital discharge, taken from the medical records and as recorded in the eCRF [Time Frame: Day 28]. Time from dosing to when a participant is discharged from the hospital.
17. Number of participants with Adverse events (AEs) and Serious adverse events (SAEs), taken from the medical records and as recorded in the eCRF [Time Frame: Up to Day 60]. An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the medicinal product. An SAE is any untoward medical occurrence, that at any dose results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, congenital anomaly/birth defect or any other important medical event that may jeopardize the participant or may require medical or surgical treatment to prevent one of the other outcomes listed before

Completion date
25/01/2021

Eligibility

Key inclusion criteria
1. Age ≥18 years and ≤79 years at the time of obtaining informed consent
2. Participants must:
2.1. Have positive SARS-CoV-2 result (any validated test, e.g. RT-PCR [performed on an appropriate specimen; e.g. respiratory tract sample])
2.2. AND be hospitalized due to diagnosis of pneumonia (chest X-ray or computerized tomography [CT] scan consistent with COVID-19)
2.3. AND be developing new-onset of oxygenation impairment requiring any of the following:
2.3.1. High-flow oxygen (≥15 l/min)
2.3.2. Non-invasive ventilation (e.g. CPAP, BiPAP)
2.3.3. Mechanical ventilation ≤48 h prior to dose
2.4. AND have increased biological markers of systemic inflammation (either CRP >ULN1 or serum ferritin >ULN1).
3. No gender restriction.
4. Female participants must meet and agree to abide by the contraceptive criteria Contraceptive use by women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. A female participant is eligible to participate if she is not pregnant or breastfeeding, and one of the following conditions applies:
4.1. Is a woman of non-childbearing potential (WONCBP) OR
4.2. Is a woman of childbearing potential (WOCBP) and using a contraceptive method that is highly effective, with a failure rate of <1%, during the study intervention period and for at least 60 days after the last dose of study intervention (sexual abstinence is acceptable if it is the participant's normal practice).
4.3. If not consistently on a highly effective method of contraception during hospitalization, the participant must agree to a highly effective contraception plan if discharged before Day 60.
4.4. The investigator should evaluate potential for contraceptive method failure (e.g. noncompliance, recently initiated) in relation to the first dose of study intervention.
4.5. A WOCBP must have a negative highly sensitive pregnancy test (urine or serum as required by local regulations) at hospital admission or before the first dose of study intervention.
4.6. The investigator is responsible for review of medical history, menstrual history, and recent sexual activity to decrease the risk for inclusion of a woman with an early undetected pregnancy.
5. Capable of giving written informed consent. If participants are not capable of giving written informed consent, alternative consent procedures will be followed as detailed in the protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Progression to death is imminent and inevitable within the next 48 hours, irrespective of the provision of treatments, in the opinion of the investigator
2. Multiple organ failure according to the investigator’s judgement or a Sequential Organ Failure Assessment (SOFA score) >10 if in the ICU
3. Extracorporeal membrane oxygenation (ECMO) hemofiltration/dialysis, or high-dose (>0.15g /kg/min) noradrenaline (or equivalent) or more than one vasopressor
4. Current serious or uncontrolled medical condition (e.g. significant pulmonary disease [such as severe COPD or pulmonary fibrosis], heart failure [NYHA class III or higher], significant renal dysfunction, acute myocardial infarction or acute cerebrovascular accident within the last 3 months) or abnormality of clinical laboratory tests that, in the investigator's judgment, precludes the participant's safe participation in and completion of the study
5. Untreated systemic bacterial, fungal, viral, or other infection (other than SARS-CoV-2)
6. Known active tuberculosis (TB), history of untreated or incompletely treated active or latent TB, suspected or known extrapulmonary TB
7. Known HIV regardless of immunological status
8. Known HBsAg and/or anti-HCV positive
9. Currently receiving radiotherapy, chemotherapy or immunotherapy for malignancy
10. Received monoclonal antibody therapy (e.g. tocilizumab, sarilumab) within the past 3 months prior to randomization, including intravenous immunoglobulin, or planned to be received during the study
11. Received immunosuppressant therapy including but not limited to cyclosporin, azathioprine, tacrolimus, mycophenolate, JAK inhibitors (e.g. baricitinib, tofacitinib, upadacitinib) within the last 3 months prior to randomization or planned to be received during the study
Note: Participants with an organ transplant are therefore excluded (except patients with corneal transplants not requiring immunosuppression).
12. History of allergic reaction, including anaphylaxis to any previous treatment with an anti-GM-CSF therapy
13. Received COVID-19 convalescent plasma within 48 hours of randomization
Note: Participants who have received COVID-19 convalescent plasma but continue to worsen in the 48 hours after infusion of the convalescent plasma, in the opinion of the investigator, will become eligible for the study
14. Currently receiving chronic oral corticosteroids for a non-COVID-19 related condition in a dose higher than prednisone 10 mg or equivalent per day
15. Treatment with an investigational drug within 30 days of randomization
16. Participating in other drug clinical trials, including for COVID-19
17. Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) >5x upper limit of normal (ULN)
18. Platelets <50,000/mm^3
19. Hemoglobin ≤9 g/dl
20. Absolute neutrophil count (ANC) <1.5 x 109/l (neutropenia ≥ Grade 2)
21. Estimated GFR ≤30 ml/min/1.73m^2
22. Pregnant or breastfeeding females

Date of first enrolment
28/05/2020

Date of final enrolment

19/10/2020

Locations

Countries of recruitment
United Kingdom

England

Argentina

Belgium

Brazil

France

Japan

Netherlands

Poland

South Africa

Spain

United States of America

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Sponsor information

Organisation
GlaxoSmithKline (United Kingdom)

ROR
https://ror.org/01xsqw823

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the Clinical Study Data Request site. Supporting Materials: Study Protocol, Statistical Analysis Plan (SAP), Informed Consent Form (ICF), Clinical Study Report (CSR). Time Frame: IPD will be made available within 6 months of publishing the results of the primary endpoints of the study. Access Criteria: Access is provided after a research proposal is submitted and has received approval from the Independent Review Panel and after a Data Sharing Agreement is in place. Access is provided for an initial period of 12 months but an extension can be granted, when justified, for up to another 12 months. URL: http://clinicalstudydatarequest.com.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		09/03/2022	23/05/2022	No	No
Basic results		16/03/2022	16/06/2022	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes