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Study to monitor the occurrence of viral variants in patients with compromised immune systems being treated for COVID-19

Submission date
18/03/2022

Recruitment status
No longer recruiting

Registration date
24/05/2022

Overall study status
Completed

Last Edited
06/06/2025

Condition category
Infections and Infestations

[X] 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.
Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19 include people who have long-term health conditions and a weakened immune system (often referred to as immunocompromised). The aim of this study is to gather clinical information about sotrovimab after it is given to immunocompromised patients who have tested positive for COVID-19. Specifically, the study is looking for clearance of the virus and, if not cleared, for the appearance of any genetic changes (mutations) in the virus following sotrovimab treatment. This medication is already approved by the MHRA (UK's Health Authority) and is available to treat patients in UK NHS facilities. Sotrovimab is also known by the brand name Xevudy. It has already been established in previous research that sotrovimab helps the body to fight COVID-19 infection. There will be about 10 NHS sites in Great Britain taking part in the study and a total of 500 patients are expected to be enrolled.

Who can participate?
Any immunocompromised patients aged 18 years and over who have tested positive for COVID-19, who are not currently hospitalised, and who have been prescribed sotrovimab treatment as part of usual care.

What does the study involve?
Patients whose doctor has decided to treat their infection with sotrovimab and who also meet the eligibility criteria for the study will be asked to consent to join the study. Once they are enrolled in the study, they will be asked to provide nasal and throat swabs and provide information on their health, medical history, vaccination status and their COVID-19 infection at four visits. The first visit will be at the time of sotrovimab treatment administration (baseline

visit) and then there are three follow-up visits which will be conducted via telephone with swabs being taken by the patient and posted to the study laboratory for analysis.

What are the possible benefits and risks of participating?
The study procedures that are not part of usual care for COVID-19 (i.e. are only being done for the study) are the four nose and throat samples. There is minimal risk from these procedures, but patients may experience some discomfort during or after the nose and throat are swabbed for sample collection.

Where is the study run from?
The study will run in UK NHS sites which are also Covid Medicines Delivery Units and are therefore able to administer sotrovimab as part of usual care.

When is the study starting and how long is it expected to run for?
March 2022 to May 2023

Who is funding the study?
GlaxoSmithKline (UK)

Who is the main contact?
1. Dr David Lowe, d.lowe@ucl.ac.uk
2. Dr Myriam Drysdale, myriam.g.drysdale@gsk.com

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2022-000754-29

Integrated Research Application System (IRAS)
1005346

Central Portfolio Management System (CPMS)
52127

Protocol serial number
218407

Study information

Scientific Title
Prospective cohort study to monitor the emergence of SARS-CoV-2 spike viral variants in immunocompromised non-hospitalised patients exposed to sotrovimab in Great Britain: the LUNAR study

Acronym
LUNAR

Study objectives
1. Evaluate the proportion of patients eligible for sequence analysis that have any amino acid (AA) change from baseline in the epitope of sotrovimab binding in samples collected at Day 7, 14 and 28 (+/-2 days)
2. Evaluate the proportion of patients eligible for sequence analysis that have any AA change from baseline in the spike protein in samples collected at Day 7, 14 and 28 (+/-2 days)

1. Evaluate the proportion of patients eligible for sequence analysis with variants of concern (VOC) and under investigation (VUI) on the earliest possible sample including baseline
2. Evaluate the proportion of patients with undetectable virus at Day 7, 14 and 28 (+/-2 days) by RT-PCR
3. Evaluate the proportion of patients with key clinical outcomes(hospital admission, requirement for respiratory support, intensive care unit [ICU] admission and death) through Day 28 post sotrovimab administration
4. Describe amino acid (AA) (detected at >5% allelic frequency)changes in the SARS-CoV-2 spike protein in samples collected at Day 7,14 and 28 (+/-2 days) compared to baseline following sotrovimab administration for samples with viral loads above the threshold of the sequencing assay
5. Describe AA changes in the consensus sequence (>50%) of SARS-CoV-2 spike protein in samples collected at Day 7, 14 and 28 (+/-2 days) compared to baseline following sotrovimab administration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/05/2022, South Central - Oxford B Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square Bristol BS1 6PN, UK; +44 (0)207 104 8360; oxfordb.rec@hra.nhs.uk), ref: 22/SC/0099

Primary study design
Interventional

Study design
Non-randomized study

Study type(s)
Other

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

Interventions
Patients will have their first nasal/oropharyngeal swab at the site on the day they receive sotrovimab (D0) and will be provided with three home test kits to complete on days 7, 14 and 28 (+/-2 days). The total duration is about 4 weeks. Concomitant medications, vaccination status and clinical outcome (i.e. including hospital admission, respiratory support, ICU admission and death) will be collected on day 0 at site and days 7, 14 and 28 during follow-up calls.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
1. Proportion of patients eligible for sequence analysis that have any amino acid change from baseline in the epitope of sotrovimab binding measured using RT-PCR on samples collected on days 7, 14 and 28 (+/-2 days)
2. Proportion of patients eligible for sequence analysis that have any amino acid change from baseline in the spike protein measured using RT-PCR on samples collected on days 7, 14 and 28 (+/-2 days)

Key secondary outcome(s)
1. Proportion of patients eligible for sequence analysis with VOC and VUI on the earliest possible sample including baseline measured using RT-PCR and sequencing methods at baseline and later timepoints on days 7, 14 and 28 (+/-2 days) if baseline samples can’t be analysed
2. Proportion of patients with undetectable virus measured using RT-PCR on days 7, 14 and 28 (+/-2 days)

3. Clinical outcomes measured on days 7, 14 and through 28 (+/-2 days):
3.1. Proportion of patients that are admitted to hospital for any cause and for COVID-19 reasons measured using electronic health records and medical charts through 28 days
3.2. Proportion of patients requiring new or increased oxygen support measured using electronic health records and medical charts through 28 days
3.3. Proportion of patients requiring invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO) measured using electronic health records and medical charts through 28 days
3.4. Proportion of all-cause ICU admission measured using electronic health records and medical charts through 28 days

Completion date
31/05/2023

Eligibility

Key inclusion criteria
1. Adult patients ≥18 years old
2. Immunocompromised (as defined in the clinical commissioning policy [MHRA, 2022])
3. A positive PCR or antigen test for SARS-CoV-2 through clinical testing or routine screening undertaken as part of clinical management
4. Prescribed treatment with sotrovimab as standard of clinical care
5. Able to provide informed consent and willing to adhere to study-related procedures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
219

Key exclusion criteria
1. Patients who require hospitalisation (related or not to COVID-19) at baseline
2. Patients who initiated sotrovimab therapy in in-patient settings
3. Patients unable to perform follow-up sample collection
4. Blinded patients from other COVID-19 related trials

From the Clinical Commissioning Policy, the following groups will also be excluded from this study unless also eligible for sotrovimab under other Clinical Commissioning Policy IC criteria not

listed below [MHRA, 2022]:
5. Cohort of patients with rare neurological conditions
6. Cohort of patients with Down's syndrome
7. In the cohort of patients with renal disease: patients with chronic kidney stage (CKD) 4 or 5 (an eGFR less than 30 ml/min/1.73 m²) without immunosuppression (patients with renal disease cohort)
8. In the cohort of patients with liver disease: patients with cirrhosis Child's-Pugh class A who are not on immunosuppressive therapy (compensated liver disease), class B or class C (decompensated liver disease)

Date of first enrolment
21/06/2022

Date of final enrolment
12/05/2023

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Guys Hospital
Guys Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
St Georges
St. Georges Hospital

117 Suttons Lane
Hornchurch
United Kingdom
RM12 6RS

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

Study participating centre
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
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G12 0XH

Study participating centre
The Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
TS1 4LP

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 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?
Results article		19/05/2025	06/06/2025	Yes	No
HRA research summary			28/06/2023	No	No