Prospective cohort study to monitor the emergence of SARSCoV-2 spike viral variants in immunocompromised nonhospitalised patients exposed to sotrovimab in Great Britain: LUNAR study (218407)

First published: 29/03/2022
Last updated: 11/07/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/49384

EU PAS number
EUPAS46386

Study ID
49384

DARWIN EU® study
No

Study countries
United Kingdom

Study description
The LUNAR study is genomic surveillance study that aims to describe changes in the SARS-CoV-2 spike protein observed in immunocompromised patients receiving sotrovimab as clinical standard of care in sentinel sites at a national level to assess the potential emergence of viral variants

Study status
Finalised

Research institution and networks

Institutions

GlaxoSmithKline (GSK)
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Institution

Contact details

Study institution contact
GSK Clinical Disclosure Advisor
Study contact

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Primary lead investigator
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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
08/12/2021
Actual:
08/12/2021

Study start date
Planned:
01/07/2022
Actual:
01/07/2022

Date of final study report
Planned:
27/02/2024

Actual:
27/02/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-218407-protocol-orig-redact.pdf(1.3 MB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
Non-EU RMP only

Methodological aspects

Study type

Study type list

Study type:
Clinical trial

If 'other', further details on the scope of the study
Genomic Surveillance study

Main study objective:

This genomic surveillance study will aim to describe changes in the SARS-CoV-2 spike protein observed in immunocompromised patients receiving sotrovimab as clinical standard of care in sentinel sites at a national level to assess potential emergence of viral variant.

Study drug and medical condition

Name of medicine
Xevudy

Study drug International non-proprietary name (INN) or common name
SOTROVIMAB

Anatomical Therapeutic Chemical (ATC) code
(J06BD05) sotrovimab

Medical condition to be studied
COVID-19

Population studied

Age groups
Adults (18 to < 46 years)
Adults (46 to < 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Special population of interest
Immunocompromised

Estimated number of subjects
500

Study design details

Outcomes
- Proportion of patients eligible for sequence analysis that have any amino acid change from Baseline in the epitope of sotrovimab binding in samples collected at Day 7, 14 and 28 (+/-2 days).
- Proportion of patients eligible for sequence analysis that have any amino acid change

from Baseline in the spike protein in samples collected at Day 7, 14 and 28 (+/-2 days), 1. % pts with SARS CoV-2 variants (VOC/VUI), % pts with undetectable virus at Day(D) 7,14,28, 3.Clinical outcomes through D28, 4.AA changes in spike protein at D7,14,28 compared to BL for samples with viral load (VL) above threshold of sequencing assay, 5.AA changes in spike consensus sequences from BL in samples where VL is insufficient but sufficient to generate consensus level sequencing data.

Data analysis plan
• Sequencing of Baseline (BL) & follow-up samples will be performed regularly. Following will be reported for patients (pts) eligible for sequencing analysis: Proportion of pts with amino acid (AA) change from BL in epitope of sotrovimab, Proportion of pts with AA change from BL in spike protein
• For samples with viral load (VL) above threshold for allelic frequency determination, AA changes in SARS-CoV-2 spike protein at >5% allelic frequency compared to BL will be reported
• For samples with VL below threshold for low (5%) allelic frequency analysis, but above threshold for consensus sequence generation, AA changes in SARS-CoV-2 spike protein consensus sequence from BL will be reported
• For patients eligible for sequencing analysis, VOC, VUI & other lineages information as classified by UKHSA & WHO will be identified from sequencing data
• Comorbidities, clinical outcomes, patients with undetectable virus & safety event data will be described & reported

Documents

Study report
CSR Anonymized 03 Jul 2024.pdf(6.23 MB)

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping
No

Data quality specifications

Check conformance
Unknown

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
No