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 institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor

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

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