A Multicenter, Multi-countiy Retrospective Cohort Study to Evaluate the Clinical Outcomes in Adults with Severe COVID-19

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Study Finalised

Administrative details

EU PAS number

EUPAS34303

Study ID

39810

DARWIN EU® study

No

Study countries

- Belgium
- France
- Hong Kong
- Italy

Korea, Democratic People's Republic of

Singapore

Spain

United Kingdom

United States

Study description

GS-US-540-5807: The primary objectives of this study were to assess the clinical course and outcome of adults with severe COVID-19 assessed by: 1) a 7-point ordinal scale on Day 14, and 2) all-cause mortality at Day 28.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

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Institution **Pharmaceutical company**

Multiple centres: 50 centres are involved in the study

Contact details

Study institution contact

Gilead Study Director ClinicalTrialDisclosure@gilead.com

Study contact

ClinicalTrialDisclosure@gilead.com

Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/03/2020

Actual: 23/03/2020

Study start date

Planned: 01/04/2020

Actual: 01/04/2020

Date of final study report

Planned: 01/04/2021

Actual: 15/01/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences

Study protocol

GS-US-540-5807-appendix-16.1.1-protocol_f-redact.pdf (186.73 KB)

GS-US-540-5807-appendix-16.1.1-protocol amendment 1_f-redact.pdf (193.8 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The primary objectives of this study were to assess the clinical course and outcome of adults with severe COVID-19 assessed by: 1) a 7-point ordinal scale on Day 14, and 2) all-cause mortality at Day 28.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

COVID-19

Population studied

Short description of the study population

Adults with severe COVID-19.

Adult participants with COVID-19 confirmed by PCR who meet the following criteria:

1. Hospitalized
2. COVID-19 confirmed by PCR
3. SpO2 ≤94% on room air or require supplemental oxygen at admission
4. Radiographic evidence of pulmonary infiltrates
5. Did not receive remdesivir (RDV) at any time during illness

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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

Other

Special population of interest, other

COVID-19 patients

Estimated number of subjects

3500

Study design details

Outcomes

1) Recovery rate assessed by a 7-point ordinal scale (Death, Hospitalized on invasive ventilation/ECMO, Hospitalized on non-invasive ventilation, Hospitalized requiring oxygen, Hospitalized not requiring oxygen but requiring ongoing medical care, Hospitalized not requiring oxygen and not requiring ongoing medical care, and Not hospitalized) on Day 14 and 2) All-cause mortality at Day 28. •Proportion of subjects with recovery at Day14 •Proportion of subjects with SpO2 > 94% at Day14 •Proportion of subjects on room air at Day14 •Proportion of subjects with negative SARS-CoV-2 PCR at Day14 •Proportion of subjects on ventilation at Day14 •Proportion of subjects with ≥1-point improvement in clinical status on Day14 • Change in O2 support status up to Day14 •Duration of hospitalization

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Data analysis plan

Retrospective Cohort Study (RCS) Data Analysis: Summary statistics were generated for the cohort overall and by contributing site/country. For categorical variables, numbers & percentages of patients were reported including the 95% confidence intervals (CI). For continuous variables, mean, standard deviation, minimum, first and third quartile (Q1, Q3), median, maximum & 95% CIs were calculated, together with the total number of observations & the number of missing values. Descriptive statistics were summarized demographics and baseline characteristics. Analysis to compare standard of care (SOC) from RCS & agents potentially active against SARC CoV-2: Data from this retrospective cohort study might be used to compare the efficacy of potential investigational antiviral agents against this cohort which did not receive such agents. Such analyses would use appropriate statistical methods for comparisons of non-randomized cohorts, such as weighted analysis & propensity score analysis.

Documents

Study results

GS-US-540-5807-csr-synopsis-final_f-redact.pdf (509.07 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Deidentified data were extracted from electronic medical record (EMR) databases, clinical registries, case series or additional sources from participating sites and countries, and then entered into a structured e-CRF system (or transferred electronically if feasible), then pooled into one database with standard data format.

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