A Multi-center, Longitudinal, Clinical Real-World Study to Evaluate Mortality and Clinical Outcomes in Hospitalized Adults with COVID-19 Infection in the United States

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/42040

EU PAS number

EUPAS35465

Study ID

42040

DARWIN EU® study

No

Study countries

United States

Study description

GS-US-540-5835: The primary objectives of this study were to estimate the mortality rate in hospitalized adults aged ≥ 18 years with coronavirus disease 2019 (COVID-19) in the United States (US) using real-world data (RWD) and to compare the mortality rate of hospitalized patients from the RWD clinical setting to patients participating in remdesivir (RDV, GS-5734™, Veklury®) studies including compassionate use.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

First published: 12/02/2024

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Institution | Pharmaceutical company

Multiple centres: 13 centres are involved in the study

Contact details

Study institution contact

Gilead Study Director

Study contact

ClinicalTrialDisclosure@gilead.com

Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 24/03/2020

Study start date

Actual: 20/01/2020

Data analysis start date

Actual: 30/03/2020

Date of interim report, if expected

Actual: 01/04/2020

Date of final study report

Planned: 30/09/2020

Actual: 10/04/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences

Study protocol

GS-US-540-5835-appendix-16.1.1-protocol_f-redact.pdf(190.88 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 estimate the mortality rate in hospitalized adults aged ≥ 18 years with coronavirus disease 2019 (COVID-19) in the United States (US) using real-world data (RWD) and to compare the mortality rate of hospitalized patients from the RWD clinical setting to patients participating in remdesivir (RDV, GS-5734™, Veklury®) studies including compassionate use.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Coronavirus test positive

Population studied

Short description of the study population

RWD from adult patients ≥ 18 years of age hospitalized in the US for COVID-19 infection will be analyzed.

Inclusion criteria will include:

1. Male or female patients aged 18 years and older
2. Patients diagnosed with the following ICD-10 codes consistent with COVID-19 (B97.29, other coronavirus as the causes of diseases classified elsewhere; B34.2, coronavirus infection, unspecified; and U07.1, 2019-nCoV acute respiratory disease)
3. Patients hospitalized after the first COVID-19 index patient was diagnosed in the US on 20 January 2020

Exclusion criteria will include:

1. Patients diagnosed with the ICD-9 code 079.89, other specific viral infections (079.89 defined patients were automatically brought into the dataset when B97.29 was used because of the ICD-9 mapping to ICD-10 terms)
2. Patients who were enrolled in a clinical trial on or after 20 January 2020

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

153

Study design details

Outcomes

1) To estimate the mortality rate in hospitalized adults aged ≥ 18 years with COVID-19 in the US using RWD and 2) To compare the mortality rate of hospitalized patients from the RWD clinical setting to patients participating in RDV studies including compassionate use, 1) To describe the health status of hospitalized adult patients with COVID-19 at baseline, defined as time of initial hospitalization, in the US and 2) To describe the changes in health status in the hospitalized patients with COVID-19 using a 6-point ordinal scale at baseline and at end of follow-up

Data analysis plan

Summary statistics were generated for the cohort overall and by baseline oxygen support status subgroup. For categorical variables, numbers and percentages of patients were reported. For continuous variables, the mean, standard deviation (SD), minimum, first and third quartile (Q1, Q3), median, and maximum were calculated, together with the total number of observations and the number of missing values. Mortality rates and Kaplan-Meier survival curves for various at-risk groups were estimated and then compared as mortality rate ratios using Poisson regression. The results are summarized in the interim study report. There are no plans to develop a final study report.

Documents

Study results

GS-US-540-5835-Summary-Report-Interim-1_f-redact.pdf(1.73 MB)

Data management

Data sources

Data source(s), other

TriNetX

Data sources (types)

Electronic healthcare records (EHR)

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