Viral SARS-CoV-2 rebounds in commercial pharmacy-based SARS-CoV-2 PCR testing

First published: 23/02/2023

Last updated: 12/09/2024

Study Finalised

Administrative details

EU PAS number

EUPAS103517

Study ID

105624

DARWIN EU® study

No

Study countries

United States

Study description

This is a non-interventional, retrospective cohort study using secondary data sources containing structured data from the US. This study will include adults (≥18 years of age) and pediatric participants (<18 years of age) with a positive

SARS-CoV-2 test (e.g. positive polymerase chain reaction (PCR) of direct SARS-CoV-2 viral testing). This study will be conducted using SARS-CoV-2 diagnostic testing data from the Helix Respiratory Registry with linkage to the retrospective Komodo Healthcare claims data during the period of June 01, 2020, to February 28, 2023. Viral SARS-CoV-2 rebound will be examined after stratification of variables such as SARS-CoV-2 therapeutic treatment, viral load patterns, high-risk status for progression to severe SARS-CoV-2, age (<50 years of age versus 50+ years of age), and by timing around rebounds in relation to initial test positivity to treatment for SARS-CoV-2.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Helix OpCo, LLC

Contact details

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Study contact

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Primary lead investigator

Scott Kelly

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/11/2022

Actual: 17/11/2022

Study start date

Planned: 22/02/2023

Actual: 23/02/2023

Data analysis start date

Planned: 14/07/2023

Actual: 14/07/2023

Date of final study report

Planned: 14/08/2024

Actual: 13/08/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C4671048 NI APPROVED PROTOCOL_FINAL_V1.0_08FEB2023_redacted.pdf
(463.38 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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

To estimate viral SARS-CoV-2 rebound rates, prior to the Omicron era and during the Omicron era, in high frequency (volume) SARS-CoV-2 diagnostic testers overall, and among those treated with Paxlovid/nirmatrelvir-ritonavir for SARS-CoV-2 versus those with no evidence of SARS-CoV-2 treatment (untreated for SARS-CoV-2).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

PAXLOVID

Medical condition to be studied

COVID-19

Population studied

Age groups

- Adolescents (12 to < 18 years)
- 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)

Estimated number of subjects

21.911

Study design details

Outcomes

SARS-CoV-2 rebound where the main definition of rebound is 1) a positive test (at the index date), followed by a single negative test, followed by a positive test within 28 days or 2) 1 or more positive tests starting at the index date, followed by 1 or more negative tests, followed by a positive test within same 28-day time span.

Data analysis plan

Descriptive statistics among individuals with SARS-CoV-2 in the Helix Respiratory Registry that overlap with the retrospective Komodo Healthcare claims data will be summarized. Means with standard deviations, medians with interquartile ranges will be provided for continuous variables. Numbers and percentages will be provided for dichotomous variables or categorical variables. For exploratory analyses, logistic regression or Cox proportional hazards regression models will be used to identify risk factors and outcomes for SARS-CoV-2 rebound in adjusted analyses. Model selection will balance biological and contextual knowledge for potential confounders with statistical considerations

for model fit and the bias versus variance tradeoff. Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a statistical analysis plan (SAP), which will be dated, filed, and maintained by the sponsor.

Documents

Study report

C4671048 Non Interventional Final Study Report_13Aug2024_R.pdf (2.23 MB)

Study, other information

C4671048 Non Interventional Study Report Abstract_13Aug2024_R.pdf (89.57 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 source(s), other

Helix Respiratory Registry United States, Komodo Healthcare claims data United States

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Unknown

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Unknown