A Multicenter, Retrospective, Observational Study Using Real-world Data to Describe the Safety, Treatment Pattern and Effectiveness of Nirmatrelvir/Ritonavir among Patients treated with Nirmatrelvir/Ritonavir in China

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/103410

EU PAS number

EUPAS103409

Study ID

103410

DARWIN EU® study

No

Study countries

☐ China

Study status

Finalised

Research institutions and networks

Institutions

Guangzhou Medical University

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Institution

Multiple centres: 9 centres are involved in the study

Contact details

Study institution contact

Ying Ma

Study contact

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Primary lead investigator

Nanshan Zhong

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 08/09/2022

Study start date

Planned: 06/03/2023

Actual: 05/12/2022

Data analysis start date

Actual: 26/02/2024

Date of interim report, if expected

Actual: 25/07/2023

Date of final study report

Planned: 17/04/2024

Actual: 07/06/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C4671043_Protocol-5Dec2022-Redacted.pdf(7.32 MB)

C4671043_Protocol-5Dec2022-full protocol.pdf(7.31 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Study design:

Retrospective observational study

Main study objective:

To describe real-world safety of nirmatrelvir/ritonavir among patients treated with nirmatrelvir/ritonavir in China.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective observational study

Study drug and medical condition

Name of medicine

PAXLOVID

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

NIRMATRELVIR

RITONAVIR

Anatomical Therapeutic Chemical (ATC) code

(J05AE30) nirmatrelvir and ritonavir

nirmatrelvir and ritonavir

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)

Estimated number of subjects

1000

Study design details

Outcomes

Incidence of AEs and SAEs with explicit attribution to nirmatrelvir/ritonavir, Proportion of patients with nirmatrelvir/ritonavir dose change due to AEs with explicit attribution to nirmatrelvir/ritonavir, Proportion of patients experiencing safety related scenarios; Treatment patterns endpoints include proportion and/or duration of nirmatrelvir/ritonavir, and/or concomitant COVID-19-related treatments, or other concomitant treatments. Effectiveness endpoints include COVID-19 disease severity progressed or death, time to alleviation of

signs/symptoms, Proportion of patients with consecutive negative tests and time to first negative test.

Data analysis plan

This study is descriptive in nature and no formal hypothesis testing will be conducted. Continuous variables will be summarized using n, mean, median, minimum, maximum, standard deviation (SD), and 25th and 75th percentiles, and in addition, 95% CI will be provided for effectiveness variables. Categorical variables will be summarized using number and percentages of each category. For continuous and categorical variables, missing data will not be imputed and will be reported as frequency and percentage. Missing data will not be included in the summary statistics. For time-to-event variables (such as time to alleviation of all targeted COVID-19 signs and symptoms), Kaplan Meier (K-M) plots will be generated, and median time will be estimated along with the corresponding 95% CI.

Documents

Study report

C4671043 Paxlovid NI Clinical Study Report_redacted.pdf(805.02 KB)

C4671043 Paxlovid NI Clinical Study Report Abstract_redacted.pdf(400.64 KB)

Data management

Data sources

Data source(s)

Other data source

Data sources (types)

Other

Data sources (types), other

Individual-level data will be retrospectively abstracted from Hospital Information System (HIS) and Laboratory Information System (LIS) to the electronic Case Report Form (eCRF).

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Not applicable