

# 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

**First published:** 16/03/2023

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS103409

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### Study ID

103410

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### DARWIN EU® study

No

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## Study countries

☐ China

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## Study status

Finalised

# Research institutions and networks

## Institutions

Guangzhou Medical University

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

Multiple centres: 9 centres are involved in the study

## Contact details

### Study institution contact

Ying Ma [ying.ma3@pfizer.com](mailto:ying.ma3@pfizer.com)

Study contact

[ying.ma3@pfizer.com](mailto:ying.ma3@pfizer.com)

## Primary lead investigator

Nanshan Zhong

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 08/09/2022

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### Study start date

Planned: 06/03/2023

Actual: 05/12/2022

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### Data analysis start date

Actual: 26/02/2024

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### Date of interim report, if expected

Actual: 25/07/2023

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### 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

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**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

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**Non-interventional study design, other**

Retrospective observational study

## Study drug and medical condition

**Name of medicine**

PAXLOVID

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

NIRMATRELVIR

RITONAVIR

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**Anatomical Therapeutic Chemical (ATC) code**

(J05AE30) nirmatrelvir and ritonavir

nirmatrelvir and ritonavir

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## 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)

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### 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.

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## 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

### 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 data source

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**Data sources (types)**

Other

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**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

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**Check completeness**

Yes

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**Check stability**

Yes

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**Check logical consistency**

Yes

## Data characterisation



**Data characterisation conducted**

Not applicable