# Post-marketing Surveillance Study of the Effectiveness and Safety of new Oral Antivirals for outpatients with mild-moderate COVID-19. (ESOA-19)

**First published:** 18/07/2022

**Last updated:** 23/04/2024

Study Planned

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/49575

**EU PAS number**

EUPAS48186

**Study ID**

49575

**DARWIN EU® study**

No

**Study countries**

Portugal

**Study description**

There is an increased lack of short- and long-term real-life effectiveness and safety data on new oral antivirals authorised and commercialised to treat COVID-19. To date, only two clinical trials have been published with data on the efficacy and safety of the use of the Paxlovid® and Lagevrio®. Since there is a public health, political, social and economic pressure to prevent severity, hospitalisation and death from COVID-19, monitoring the effectiveness and safety of commercialised oral antiviral therapies against COVID-19 has become emergent pharmacovigilance and public health task. The objective of the study is to monitor the post-marketing safety and effectiveness of the new oral antivirals indicated for the treatment of COVID-19, namely Nirmatrelvir/Ritonavir (Paxlovid®) and Molnupiravir (Lagevrio®), having as holders of the Authorization of Market introduction to Pfizer Europe MA EEIG and Merck Sharp & Dohme B.V., respectively.

**Study status**

Planned

# Research institutions and networks

## Institutions

### Porto Pharmacovigilance Centre, Faculty of Medicine, University of Porto (UFPorto)

Portugal

**First published:** 17/11/2010

**Last updated:** 12/06/2023

Institution | Educational Institution | ENCePP partner

## Contact details


**Study institution contact**

Renato Ferreira da Silva

Study contact

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**Primary lead investigator**

Renato Ferreira da Silva

Primary lead investigator


## Study timelines

**Date when funding contract was signed**

Planned: 11/07/2022

Actual: 11/07/2022

**Study start date**

Planned: 01/08/2022

**Data analysis start date**

Planned: 01/09/2022

**Date of interim report, if expected**
Planned: 30/06/2024

**Date of final study report**
Planned: 30/09/2024

## Sources of funding

- EU institutional research programme

## More details on funding

Portuguese national funds and Community funds from the European Social Fund (ESF) through FCT – Fundação para a Ciência e a Tecnologia (Portugal)).

## 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

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

To generate real-world evidence on the effectiveness and safety of COVID-19 oral antiviral medicines, therefore contributing to support informed political, regulatory and clinical decisions.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Prescription event monitoring

## Study drug and medical condition

**Name of medicine**

PAXLOVID

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**Name of medicine, other**

Lagevrio

**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)

**Special population of interest**

Hepatic impaired

Immunocompromised

Renal impaired

**Estimated number of subjects**

107

## Study design details

**Outcomes**

Safety outcomes: the incidence of AE (with particular focus on AE of special interest) that emerge during or after the treatment period, serious AE, and AE leading to discontinuation of the treatment, as coded according to the MedDRA.

Effectiveness outcomes: the incidence of hospitalisation for any cause (defined as ≥24 hours of acute care in a hospital or any similar facility) or death for any, Adherence to treatment: will be measured using the self-reported 7-item Measure Treatment Adherence (MTA) tool validated for the Portuguese Population9. The MTA is a psychometric tool derived from the Morisky et al. questionnaire and evaluates the individuals` behaviour concerning the daily use of medication.

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**Data analysis plan**

A descriptive analysis will be conducted on all study variables. Categorical variables will be described through absolute and relative frequencies, and continuous variables will be described by descriptive statistics using mean and standard deviation, quartiles, median value, and minimum and maximum values. Demographic and screening data will be described using the descriptive measures defined above and according to each variable type. Clinical information recorded at baseline visit will also be described to all subjects Univariate and multivariate regression analyses will be performed to evaluate the relationship between the presence of risk factors and AE. Survival analysis will be conducted for time until hospitalization and until dead (total and medicines related) and until AE. A propensity score model will be applied to compare the safety and effectiveness of the different oral antivirals.

# Data management

# ENCePP Seal

**This study has been awarded the ENCePP seal**

**Conflicts of interest of investigators**

EUPAS48186-48194.pdf(160.73 KB)

**Composition of steering group and observers**

Composition of Steering Group and Observers_signed.pdf(400.67 KB)

# Data sources

**Data sources (types)**

Drug dispensing/prescription data

Other

**Data sources (types), other**

Prospective patient-based data collection, prescription event monitoring

# 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