# Safety of Paxlovid During Pregnancy

**First published:** 14/12/2022

**Last updated:** 20/08/2024





### Administrative details

| <b>EU PAS number</b> |  |
|----------------------|--|
| EUPAS50117           |  |
| Study ID             |  |
| 50118                |  |
| DARWIN EU® study     |  |
| No                   |  |
| Study countries      |  |
| France               |  |
| Spain                |  |
| United Kingdom       |  |
|                      |  |

### **Study description**

This study aims to answer the research question what are the prevalence and comparative safety of adverse pregnancy, offspring, and maternal outcomes in

women exposed to Paxlovid during pregnancy? The primary study objective is to estimate the birth prevalence, prevalence ratio, and prevalence difference of the following adverse pregnancy, offspring, and maternal outcomes in women who are exposed to Paxlovid during pregnancy compared with those in women who are exposed to molnupiravir, where available, during pregnancy or to neither Paxlovid nor molnupiravir during pregnancy: spontaneous abortion, elective termination, stillbirth, preterm delivery (pregnancy outcomes), major congenital malformations, intrauterine growth retardation/small for gestational age (offspring outcomes), gestational diabetes, postpartum haemorrhage, maternal death (maternal outcomes). The study will focus on pregnant women. Within this population, there will be a descriptive analysis and comparative analyses. Molnupiravir, an antiviral with a similar recommended usage, will be used as an active comparator in the data sources in which it is available, other drugs may be incorporated as active comparators as more information becomes available. A second comparator group is included in the study: individuals with COVID-19 unexposed to any study medication. This PASS will make secondary use of several data sources from electronic health records and/or claims data in European countries that have the ability to capture Paxlovid exposure and where the target populations, study outcomes, and key covariates can be ascertained.

#### **Study status**

Ongoing

Research institutions and networks

Institutions

# Pfizer First published: 01/02/2024 Last updated: 01/02/2024 Institution University Medical Center Utrecht (UMCU) Netherlands **First published:** 24/11/2021 **Last updated:** 22/02/2024 Institution **Educational Institution** Hospital/Clinic/Other health care facility **ENCePP** partner RTI Health Solutions (RTI-HS) France □ Spain Sweden ☐ United Kingdom United Kingdom (Northern Ireland) **United States First published:** 21/04/2010 **Last updated:** 13/03/2025

# Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

□ Spain

**First published:** 05/10/2012

**Last updated:** 23/05/2025

Institution

**Educational Institution** 

Laboratory/Research/Testing facility

**Not-for-profit** 

**ENCePP** partner

# Bordeaux PharmacoEpi, University of Bordeaux

France

**First published:** 07/02/2023

**Last updated:** 08/02/2023

Institution

**Educational Institution** 

Hospital/Clinic/Other health care facility

**Not-for-profit** 

**ENCePP** partner

### Agenzia regionale di sanità della Toscana (ARS)

☐ Italy

First published: 01/02/2024

Last updated: 12/03/2024

Institution EU Institution/Body/Agency ENCePP partner

### **Networks**

| The SIGMA Consortium (SIGMA)    |  |  |  |
|---------------------------------|--|--|--|
| ☐ Denmark                       |  |  |  |
| European Union                  |  |  |  |
| France                          |  |  |  |
| Germany                         |  |  |  |
| Italy                           |  |  |  |
| Netherlands                     |  |  |  |
| Norway                          |  |  |  |
| Spain                           |  |  |  |
| Sweden                          |  |  |  |
| United Kingdom                  |  |  |  |
| First published: 10/02/2013     |  |  |  |
| <b>Last updated:</b> 16/12/2024 |  |  |  |
| Network ENCePP partner          |  |  |  |

### Contact details

**Study institution contact** 

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Study contact

sampada.gandhi@pfizer.com

### **Primary lead investigator**

Sampada Gandhi

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 18/03/2022

Actual: 18/03/2022

#### Study start date

Planned: 28/02/2024

Actual: 28/02/2024

#### Date of final study report

Planned: 31/03/2026

### Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Pfizer

### Study protocol

C4671037\_PROTOCOL AMENDMENT 1\_V2\_10NOV2022.pdf (8.73 MB)

C4671037\_PROTOCOL AMENDMENT 3\_V4\_21JUN2023.pdf (1.21 MB)

# Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

# Methodological aspects

Study type

Study type list

**Study topic:** 

Human medicinal product

Study type:

Non-interventional study

### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

#### **Data collection methods:**

Secondary use of data

#### Main study objective:

Estimate birth prevalence, prevalence ratio, and prevalence difference of adverse pregnancy, maternal and birth outcomes in pregnant women with COVID-19 exposed to Paxlovid compared with pregnant women with COVID-19 exposed to molnupiravir, other COVID-19 treatments or unexposed to any treatment.

# Study Design

### Non-interventional study design

Cohort

# 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**

(J05AE) Protease inhibitors

Protease inhibitors
(J05AE30) nirmatrelvir and ritonavir
nirmatrelvir and ritonavir

#### Medical condition to be studied

Abortion spontaneous

Abortion induced

Stillbirth

Congenital anomaly

Foetal growth restriction

Small for dates baby

Gestational diabetes

Postpartum haemorrhage

Maternal death

#### Additional medical condition(s)

Elective termination of pregnancy, congenital malformations

# Population studied

#### Age groups

Preterm newborn infants (0 - 27 days)

Term newborn infants (0 - 27 days)

Infants and toddlers (28 days - 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

### Special population of interest

### Study design details

#### **Outcomes**

Birth prevalence, prevalence ratio, and prevalence difference of spontaneous abortion, elective termination, stillbirth, preterm delivery (pregnancy outcomes), major congenital malformations, intrauterine growth retardation/small for gestational age (offspring outcomes), gestational diabetes, postpartum haemorrhage, maternal death (maternal outcomes).

#### Data analysis plan

The study will have a cohort design. Focusing on the target populations, the descriptive component will include tabulations of age, sex, comorbidities, selected concurrent medications, COVID-19 vaccination status, history of COVID-19, current COVID-19 status and setting of Paxlovid use (among Paxlovid users). Comparative analyses will be based on the estimation of risk/prevalence, risk/prevalence ratios, and risk/prevalence differences. Comparative analyses will control for measured confounding within each data source. Aggregated results from each data source will be combined using metanalytic techniques as numbers allow. If a study population is too small, analyses will be only descriptive, pooling of results from various data sources will be undertaken only if at least 3 independent data points are available.

### **Documents**

#### **Study report**

EUPAS50117-50126.pdf (1.8 MB)

#### Study, other information

1037\_DeclarationofInterests-Annex5\_template Sampada Gandhi.pdf (93.39 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)

The Information System for Research in Primary Care (SIDIAP)

Système National des Données de Santé (French national health system main database)

Clinical Practice Research Datalink

#### Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Electronic healthcare records (EHR)

# Use of a Common Data Model (CDM)

#### **CDM** mapping

| CDM | B4  |      |    |
|-----|-----|------|----|
| CDM | Mal | opin | gs |

#### **CDM** name

ConcepTION CDM

#### **CDM** website

https://www.imi-conception.eu/

### **CDM** release frequency

6 months

# Data quality specifications

#### **Check conformance**

Unknown

### **Check completeness**

Unknown

### **Check stability**

Unknown

### **Check logical consistency**

Unknown

### Data characterisation

### **Data characterisation conducted**

No