Safety of Paxlovid During Pregnancy

First published: 14/12/2022

Last updated: 20/08/2024

Study Ongoing

Administrative details

EU PAS number

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

Institution | Not-for-profit | ENCePP partner

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

Last updated: 16/12/2024

Network | ENCePP partner

Contact details

Study institution contact

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Study contact

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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

Pregnant women

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 meta-analytic 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)

1037_DeclarationofInterests_combined.pdf(3.03 MB)

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

Yes

CDM Mappings

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