Use and Safety of Paxlovid During Pregnancy

First published: 14/12/2022
Last updated: 25/06/2024

Study   Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50118

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.
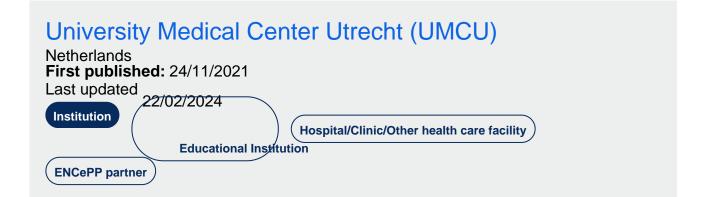
Study status
Ongoing

Research institution 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 19/02/2024

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 23/02/2024

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 16/07/2024

Network   ENCePP partner

Contact details

Study institution contact

Sampada Gandhi

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 data collection

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
(J05AE30) 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

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 data (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