A Post-Authorisation Safety Study (PASS) of ABRYSVO (Respiratory Syncytial Virus Stabilised Prefusion Subunit Vaccine) in Pregnant Women and their Offspring in a Real World Setting in Europe and UK

First published: 13/01/2025

Last updated: 12/02/2025

Study Planned

Administrative details

EU PAS number

EUPAS1000000399

Study ID

1000000399

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] France

- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

Study description

This study is a retrospective comparative cohort study of pregnant women who receive ABRYSVO between 24-36 weeks of gestation compared to pregnant women who do not receive ABRYSVO at any time during their pregnancy. In addition, analyses will be stratified by immunocompromised status and high-risk pregnancies.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

EpiChron Research Group on Chronic Diseases, Aragon Health Sciences Institute (IACS)

Spain

First published: 17/02/2017

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

Drug Safety Research Unit (DSRU)

United Kingdom

First published: 10/11/2021

Last updated: 16/02/2024

Institution | Not-for-profit | ENCePP partner

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

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

First published: 07/01/2022

Last updated: 24/07/2024

Institution | Laboratory/Research/Testing facility | 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

The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

Spain

First published: 01/02/2024

Last updated: 05/11/2024

Institution

Aarhus University

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University of Oslo

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Teamit Institute

Spain

First published: 12/03/2024

Last updated: 12/03/2024

Institution | Other | ENCePP partner

Networks

Vaccine monitoring Collaboration for Europe (VAC4EU)

- [ ] Belgium
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

First published: 22/09/2020

Last updated: 22/09/2020

Network | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Cynthia De Luise

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/03/2024

Actual: 14/03/2024

Study start date

Planned: 15/01/2025

Data analysis start date

Planned: 31/03/2029

Date of interim report, if expected

Planned: 31/12/2026

Date of final study report

Planned: 28/09/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer 100%

Study protocol

C3671026_RSV VACCINE MATERNAL PROTOCOL_V2.0_06AUG2024.pdf(1.83 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)

Other study registration identification numbers and links

C3671026

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This study is a retrospective comparative cohort study of pregnant women who receive ABRYSVO compared with an unexposed pregnant comparator group.

Main study objective:

The primary study objective is to estimate the incidence, birth prevalence, prevalence ratios and risk ratios (depending on the specific outcome) and time between vaccination and birth (live or non-live) of the following adverse pregnancy, maternal and birth outcomes in women who receive ABRYSVO during pregnancy (and their offspring), compared with a matched group of pregnant women who do not receive ABRYSVO during pregnancy (and their offspring).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

ABRYSVO

Anatomical Therapeutic Chemical (ATC) code

(J07BX05) respiratory syncytial virus vaccines

respiratory syncytial virus vaccines

Population studied

Short description of the study population

We will select females from the data sources, who are pregnant at or beyond the 24th week of gestation after the launch of ABRYSVO. We will use the ConcePTION pregnancy algorithm to estimate the start and end date of pregnancy, or data analysis plan-specific algorithms if they exist. We will include ongoing pregnancies to avoid selection bias towards pregnancies that ended prematurely. In some data sources, pregnancy is only observed when pregnancy has ended, in that instance we will include only pregnancies that have at least 10 months of administrative follow up from the last menstrual period. These 10 months cover the gestational period plus a month to identify outcomes in offspring at birth.

Age groups

Adults (18 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

600

Study design details

Setting

The setting for this study will include data sources from the VAC4EU multinational network. The VAC4EU study network comprises research organisations, public health institutes, and data access providers under the condition of being qualified and able to provide either access to relevant data and/or relevant expertise to the post-marketing monitoring of vaccines.

Comparators

1) Women of any age who are pregnant;
2) date of LMP +24 weeks is after start of study period (24 Aug 2023);
3) enrolled in the healthcare system for at least 12 months prior to time zero;
4) not vaccinated with Abrsyvo during pregnancy at matched time zero;
5) at least one day of follow up for maternal outcomes 6) at least 10 months of follow up for pregnancy and birth outcomes.

Outcomes

Pregnancy outcomes:
- Preterm delivery or birth (less than 37 weeks) among livebirths classified as extremely preterm delivery or birth (less than 28 weeks), very preterm delivery or birth (28 to less than 32 weeks), and moderate to late preterm delivery or birth (32 to less than 37 weeks);
- Time between vaccination and birth among live and non-live births (vaccination date for the unvaccinated pregnant woman is the vaccination date of their matched vaccinated pregnant woman);
- Stillbirth among live and non-live births.

Maternal outcomes during pregnancy:
- Hypertensive disorders of pregnancy;
- Guillain-Barré Syndrome (GBS).

Birth outcomes (at birth):

- Low birth weight among live births;
- Small for gestational age among live births.

Data analysis plan

Description of baseline characteristics for ABRYSVO exposed and comparator cohorts will be reported as means, standard deviations, medians and other quartiles for continuous variables and as counts and proportions for categorical variables. Missingness of lifestyle factors will also be described, as well as the duration of the look-back period. To describe the comparability of matched cohorts, we will estimate standardised differences
between ABRYSVO exposed and matched non-exposed cohorts for each baseline characteristic. For categorical variables with more than 2 levels, we will calculate an overall standardised difference across all levels. For pregnancy and birth outcomes, risk, prevalence and 95% confidence intervals (CIs) will be reported, for the time interval between vaccination and delivery, median and distributions will be provided. Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a statistical analysis plan (SAP), which will be dated, filed and maintained by the sponsor.

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 Valencia Health System Integrated Database

The Information System for Research in Primary Care (SIDIAP)

EpiChron Cohort

Norwegian Health Registers

Danish Health Data Registries

PHARMO Data Network

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)

Population registry

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

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No