A Post-Marketing Safety Study to Evaluate the Safety of Respiratory Syncytial Virus Vaccine (ABRYSVO™) Exposure During Pregnancy in an Integrated Healthcare System in the United States (C3671042)

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Study Planned

Administrative details

EU PAS number

EUPAS1000001074

Study ID

1000001074

DARWIN EU® study

No

Study countries

United States

Study description

The overall research question is: what is the risk of preterm birth, hypertensive disorders of
pregnancy, and other pre-specified adverse pregnancy, maternal, and neonatal/infant outcomes following exposure to respiratory syncytial virus prefusion F vaccine (RSVpreF) [Brand name: ABRYSVO™] during pregnancy?
The primary objective is to estimate the risk of (1) preterm birth, and (2) hypertensive disorders of pregnancy following exposure to ABRYSVO™ during pregnancy.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

Kaiser Permanente Northern California (KPNC)

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: 30/05/2024

Actual: 30/05/2024

Study start date

Planned: 30/09/2026

Data analysis start date

Planned: 09/09/2028

Date of interim report, if expected

Planned: 31/03/2027

Date of final study report

Planned: 08/03/2029

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

C3671042_RSV VACCINE PROTOCOL AMENDMENT 3 VERSION 3.1_03FEB2026.pdf (1.82 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

C3671042

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 is a retrospective, real-world, non-interventional cohort study using electronic medical record data from Kaiser Permanente Northern California to compare pregnancy, maternal, and neonatal outcomes among pregnant individuals exposed or unexposed to Respiratory Syncytial Virus Vaccine (ABRYSVO™)

Main study objective:

The primary objective of the study is to estimate the risk of preterm birth and hypertensive disorders of pregnancy following exposure to Respiratory Syncytial Virus Vaccine (ABRYSVO™) during pregnancy. The study compares outcomes among pregnant individuals exposed to ABRYSVO™ with those who are unexposed.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ABRYSVO

Anatomical Therapeutic Chemical (ATC) code

(J07BX05) respiratory syncytial virus vaccines

respiratory syncytial virus vaccines

Population studied

Short description of the study population

The study population comprises pregnant individuals aged 15 to 54 years who are members of Kaiser Permanente Northern California (KPNC) and who reach 32 weeks (32 0/7 weeks) of gestation between September 22, 2023, and September 22, 2027. Eligible participants must have had at least one prenatal visit before 20 weeks of gestation and continuous health plan enrollment with medical and pharmacy benefits from at least 90 days before pregnancy onset through delivery or pregnancy outcome. Pregnancies exposed to Respiratory Syncytial Virus Vaccine (ABRYSVO™) before 32 weeks of gestation or exposed to another Respiratory Syncytial Virus (RSV) vaccine during pregnancy are excluded. The study includes both a pregnancy cohort, consisting of eligible ABRYSVO™-exposed and unexposed pregnancies, and an infant cohort that includes all live-born infants from those eligible pregnancies. Study data are derived from routinely collected electronic medical records within KPNC, an integrated healthcare system serving more than 4.5 million members in Northern California.

Special population of interest

Pregnant women

Study design details

Setting

The study is conducted within Kaiser Permanente Northern California, an integrated healthcare delivery system serving more than 4.5 million members. The organization maintains comprehensive electronic medical records that capture vaccination, prenatal care, delivery, maternal health, and infant health information, enabling longitudinal follow-up of pregnancies and live-born infants during routine clinical care. The study uses data collected in real-world clinical practice across Northern California and leverages the Kaiser Permanente Northern California pregnancy database and electronic medical record systems to identify exposures, outcomes, and relevant covariates.

Comparators

The comparator group consists of pregnant individuals who are not exposed to ABRYSVO™. For neonatal and infant outcomes, the comparator group consists of infants from pregnancies unexposed to ABRYSVO™.

Outcomes

The primary outcomes are preterm birth and hypertensive disorders of pregnancy following exposure to Respiratory Syncytial Virus Vaccine (ABRYSVO™) during pregnancy. Secondary outcomes include pregnancy-related outcomes (such as stillbirth, premature labor, premature rupture of membranes, preterm premature rupture of membranes, cesarean delivery, prolonged maternal length of stay, and placental abruption), maternal outcomes (including thrombocytopenia, Guillain-Barré Syndrome, other immune-mediated demyelinating conditions, polyneuropathies, atrial fibrillation, and all-cause maternal mortality), and neonatal/infant outcomes (including small for gestational age, large for gestational age, low birth weight, neonatal intensive care unit admission, mechanical ventilation, and neonatal death).

Data analysis plan

The interim analysis will provide descriptive summaries of maternal and infant characteristics and calculate incidence rates for all primary, pregnancy-related, maternal, and neonatal/infant outcomes among Respiratory Syncytial Virus Vaccine (ABRYSVO™)-exposed and unexposed pregnancies. The final analysis will use Cox regression models for pregnancy-related and maternal outcomes and logistic regression for neonatal/infant outcomes, adjusting for relevant covariates to compare risks between ABRYSVO™-exposed and unexposed pregnancies.

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), other

Kaiser Permanente Northern California (KPNC)

Data sources (types)

Electronic healthcare records (EHR)

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

Unknown