A Post-Marketing Safety Study using a Pregnancy Registry to Evaluate the Safety of Respiratory Syncytial Virus Vaccine (ABRYSVO™) Exposure During Pregnancy (C3671041)

First published: 07/06/2024

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000179

Study ID

1000000179

DARWIN EU® study

No

Study countries

United States

Study description

The research question is: What is the risk of adverse pregnancy outcomes, including preterm birth, hypertensive disorders of pregnancy, and other maternal and neonatal/infant outcomes, following exposure to ABRYSVO between 32 weeks 0 days and 36 weeks 6 days of gestation in the CorEvitas RSV Vaccine Pregnancy Registry (RSV-PR)?
The primary study objective is to estimate the risk of (1) preterm birth and (2) hypertensive disorders of pregnancy following exposure to ABRYSVO between 32 weeks 0 days and 36 weeks 6 days of gestation.

The secondary study objective is to estimate the risk of the following other safety outcomes of interest following exposure to ABRYSVO between 32 weeks 0 days and 36 weeks 6 days of gestation:
(1) pregnancy-related outcomes: stillbirth, premature labor, premature rupture of membranes (PROM), preterm premature rupture of membranes (PPROM), cesarean delivery, prolonged maternal duration of hospital stay,
(2) maternal outcomes: thrombocytopenia, Guillain-Barré Syndrome (GBS), other immune-mediated demyelinating conditions, polyneuropathies, atrial fibrillation, maternal death, and
(3) neonatal/infant outcomes: small for gestational age (SGA), large for gestational age, low birth weight (LBW), admission to a neonatal intensive care unit (NICU), NICU duration of stay, mechanical ventilation in neonatal period, neonatal death, postnatal growth at 1 year of age.

The exploratory study objective is to describe the most frequently reported maternal adverse events (AEs) following exposure to ABRYSVO between 32 weeks 0 days and 36 weeks 6 days of gestation.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

CorEvitas

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ruyue Zhang

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/09/2023

Actual: 19/09/2023

Study start date
Planned: 31/07/2024

Actual: 31/07/2024

Data analysis start date
Planned: 01/10/2030

Date of interim report, if expected
Planned: 30/11/2024

Date of final study report
Planned: 30/09/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer 100%

Study protocol

C3671041_RSV VACCINE PROTOCOL AMENDMENT 1 V2.0_15MAY2024.pdf (309.99 KB)

C3671041_PROTOCOL AMENDMENT 4 V5.0_13MAY2026.pdf (505.67 KB)
C3671041_PROTOCOL AMENDMENT 3 VERSION 4.0_06JAN2026.pdf (423.54 KB)
C3671041_PROTOCOL AMENDMENT 2 VERSION 3.0_28OCT2025.pdf (422.7 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

C3671041

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

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 will be a US-based, observational, secondary database cohort study using primary data collected by the RSV-PR.

Main study objective:

The research question is:
What is the risk of adverse pregnancy outcomes, including preterm birth, hypertensive disorders of pregnancy, and other maternal and neonatal/infant outcomes, following exposure to ABRYSVO between 32 weeks 0 days and 36 weeks 6 days of gestation?
The primary study objective is to estimate the risk of
(1) preterm birth and
(2) hypertensive disorders of pregnancy, following exposure to ABRYSVO between 32 weeks 0 days and 36 weeks 6 days of gestation.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ABRYSVO

Medicinal product name, other

Respiratory syncytial virus vaccine (bivalent, recombinant)

Study drug International non-proprietary name (INN) or common name

RESPIRATORY SYNCYTIAL VIRUS, SUBGROUP A, STABILIZED PREFUSION F PROTEIN 847A

RESPIRATORY SYNCYTIAL VIRUS, SUBGROUP B, STABILIZED PREFUSION F PROTEIN 847B

Anatomical Therapeutic Chemical (ATC) code

(J07BX05) respiratory syncytial virus vaccines

respiratory syncytial virus vaccines

Medical condition to be studied

Respiratory syncytial virus infection

Stillbirth

Premature labour

Premature rupture of membranes

Preterm premature rupture of membranes

Premature separation of placenta

Caesarean section

Thrombocytopenia

Guillain-Barre syndrome

Autoimmune demyelinating disease

Polyneuropathy

Atrial fibrillation

Death

Low birth weight baby

Overweight

Additional medical condition(s)

Prevention of respiratory syncytial virus

Population studied

Short description of the study population

The study population will include 2 cohorts of individuals enrolled in the RSVPR:
(1) those exposed to ABRYSVO between 32 weeks 0 days and 36 weeks 6 days and
(2) those unexposed to ABRYSVO during pregnancy.

Age groups

- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)

Special population of interest

Pregnant women

Study design details

Setting

This study will use data collected as part of the RSV-PR.
The RSV-PR will collect data from participants and the healthcare providers (HCPs) involved in their care or the care of their infants via concise data collection forms at pre-defined timepoints during pregnancy, at pregnancy outcome, and up to 1 year of infant age.

Comparators

Comparators must be enrolled in the RSV-PR, for which the following inclusion criteria apply:

(a) a resident of the US at enrollment,

(b) 18 to 50 years of age at enrollment,

(c) gestational age greater than or equal to 32 weeks 0 days at enrollment,

(d) evidence of a personally signed and dated informed consent document or, upon waiver of written consent by the relevant IRB/independent ethics committee (IEC), verbal consent indicating that the individual (or a legally acceptable representative) has been informed of all pertinent aspects of the study,

(e) authorization obtained for the relevant health care providers to provide data to the registry, and

(f) contact information available (for participant and health care provider).

Individuals excluded from the RSV-PR will not be included in the study (this includes individuals who meet any of the following:

(a) receipt of an RSV vaccine during pregnancy before 32 weeks 0 days gestation,

(b) multi-fetal pregnancy, or

(c) enrolled in the RSV-PR with a previous pregnancy.

Comparators are not exposed to ABRYSVO during pregnancy.

Outcomes

Pregnancy related outcomes: preterm birth, hypertensive disorders of pregnancy, gestational hypertension, preeclampsia/eclampsia, HELLP (hemolysis, elevated liver enzymes and low platelets) syndrome, chronic hypertension superimposed with preeclampsia/eclampsia, postpartum hypertension, cesarean delivery, premature labor (without preterm delivery), premature rupture of membranes, preterm premature rupture of membranes,

stillbirth, prolonged maternal duration of hospital stay

Maternal outcomes: Thrombocytopenia, Guillain-Barré syndrome (GBS), polyneuropathies (excluding GBS), other immune-mediated demyelinating conditions, atrial fibrillation, maternal death, most frequently reported maternal adverse events (exploratory outcome)

Neonatal/infant outcomes: small for gestational age, large for gestational age, low birth weight, admission to a neonatal intensive care unit, mechanical ventilation in the neonatal period, neonatal death, postnatal growth deficiency at 1 year of age.

Data analysis plan

Participant characteristics will be summarized with descriptive statistics for each cohort. Comparative analyses will be conducted for each outcome, if sample size permits.

Supplementary analyses will be conducted that include pregnant individuals who were excluded from the analysis population (i.e., those lacking health care provider confirmation of ABYRSVO exposure, pregnancy, or outcomes of interest).

If sample size permits, subgroup and sensitivity analyses will be performed to examine the extent to which changes in certain methods or assumptions affect the results.

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

This study will use data collected as part of the CorEvitas RSV Vaccine Pregnancy Registry (RSV-PR).
The RSV-PR will collect data from participants and the health care providers involved in their care or the care of their infants via concise data collection forms at pre-defined timepoints during pregnancy, at pregnancy outcome, and up to 1 year of infant age.

Data sources (types)

Pregnancy registry

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