Observational Cohort Study Evaluating Real-World ABRYSVO Vaccine Effectiveness and Impact Against Medically-Attended RSV-related and All-Cause Outcomes Among Infants Born to Individuals Vaccinated During Pregnancy

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000295

Study ID

1000000295

DARWIN EU® study

No

Study countries

United States

Study description

This study will be conducted in collaboration with an integrated delivery health care organization in the United States using electronic medical record (EMR) data, collected during routine standard of care clinical encounters. This study will use a retrospective cohort design to study the vaccine effectiveness (VE) and impact of ABRYSVO vaccination during pregnancy in a real-world population over multiple RSV seasons.

Study status

Ongoing

Research institutions and networks

Institutions

Kaiser Permanente Northern California (KPNC)

Networks

Kaiser Permanente Northern California

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicola Klein

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/06/2024

Actual: 13/11/2024

Study start date

Planned: 01/12/2025

Actual: 01/12/2025

Date of final study report

Planned: 31/03/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer INC

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

C3671048

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study topic, other:

Vaccine effectiveness

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This study will use a retrospective cohort design to assess ABRYSVO VE and impact in a large, diverse, real-world setting. This NI study will be conducted within an integrated delivery health care organization using EMR data, collected during routine standard of care clinical encounters.

Main study objective:

The overall aim of this study is to evaluate the effectiveness and impact of maternal ABRYSVO vaccination during pregnancy for the prevention of medically-attended (MA) respiratory syncytial virus (RSV)-associated and all-cause infant outcomes in a large, diverse, real-world population.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

The primary objective is to estimate VE of ABRYSVO vaccination during pregnancy against RSV LRTD among infants from birth to ≤180 days of age. The key secondary objective is to estimate VE of ABRYSVO vaccination during pregnancy against RSV LRTD hospitalization among infants from birth to ≤180 days of age. Key secondary objectives include: 1) To estimate VE of ABRYSVO vaccination during pregnancy against RSV among infants from birth to ≤180 days of age. 2) To estimate VE of ABRYSVO vaccination during pregnancy

against RSV hospitalization among infants from birth to ≤180 days of age. 3) To estimate VE of ABRYSVO vaccination during pregnancy against all-cause LRTD among infants from birth through the RSV season (to ≤180 days of age). 4) To estimate VE of ABRYSVO vaccination during pregnancy against all-cause LRTD hospitalization among infants from birth through the RSV season (to ≤180 days of age). 5) To estimate VE of ABRYSVO vaccination during pregnancy against acute otitis media among infants from birth through the RSV season (to ≤180 days of age). 6) To estimate VE of ABRYSVO vaccination during pregnancy against first antibiotic prescription among infants from birth through the RSV season (to ≤180 days of age). 7) To estimate VE and interval-specific VE of ABRYSVO vaccination during pregnancy against RSV among infants from birth to ≤360 days of age. 8) To estimate VE and interval-specific VE of ABRYSVO vaccination during pregnancy against RSV hospitalization among infants from birth to ≤360 days of age. 9) To estimate VE and interval-specific VE of ABRYSVO vaccination during pregnancy against RSV LRTD among infants from birth to ≤360 days of age. 10) To estimate VE and interval-specific VE of ABRYSVO vaccination during pregnancy against RSV LRTD hospitalization among infants from birth to ≤360 days of age.

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 will comprise eligible maternal-infant pairs over a 2-year study period, identified from EMR records in the existing databases, which accrue in real-time as pregnancies/births occur. All pregnancies that reach 32 weeks of gestation during the 2-year study period, from September 22, 2023 (start of ABRYSVO vaccination season 1 as of the date of the ACIP recommendation) to January 31, 2025 (estimated end of ABRYSVO vaccination season 2) will be eligible for inclusion, along with all live born infants from the eligible pregnancies.

Age groups

- Neonate
  - Preterm newborn infants (0 – 27 days)
  - Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)

Estimated number of subjects

39456

Study design details

Setting

The study setting will be KPNC, which is an integrated delivery healthcare organization in Northern California with over 4.5 million members and approximately 40,000 births each year. KPNC members receive almost all their health care within KPNC clinics, hospitals, pharmacies, and laboratories. Information from encounters within these clinical settings are captured in EMRs which can be linked at an individual level across KPNC settings using a unique

medical record number (MRN). The KPNC pregnancy database will be used to identify the maternal-infant study population. This database links records of newborn infants with their mother, enabling integration of maternal data from across pregnancy and delivery encounters, along with infant birth information and longitudinal follow-up for infants who remain enrolled with KPNC. Infant healthcare encounters after the birth and throughout the follow-up period will be identified in the EMR. As routinely-recommended vaccinations are provided free of charge to KPNC members and can be electronically linked with the pregnancy database and other EMR data, the receipt and gestational timing of ABRYSVO vaccination during pregnancy can be determined.

Outcomes

Medically-Attended Endpoints

Primary: PCR-confirmed RSV LRTD occurring ≤180 days after birth (first episode).

Key Secondary: PCR-confirmed RSV LRTD hospitalization occurring ≤180 days after birth (first episode).

Secondary. Follow-up from birth to 180 days of age: PCR-confirmed RSV occurring ≤180 days after birth (first episode), PCR-confirmed RSV hospitalization occurring ≤180 days after birth (first episode), LRTD (any cause) occurring ≤180 days after birth (first episode during the RSV season), LRTD hospitalization (any cause) occurring ≤180 days after birth (first episode during the RSV season), Acute otitis media occurring ≤180 days after birth (first episode during the RSV season), First antibiotic prescriptions occurring ≤180 days after birth (first prescription during the RSV season).

Follow-up from birth to 360 days of age: PCR-confirmed RSV occurring ≤360 days

after birth (first episode), PCR-confirmed RSV hospitalization occurring ≤360 days after birth (first episode), PCR-confirmed RSV LRTD occurring ≤360 days

after birth (first episode), PCR-confirmed RSV LRTD hospitalization occurring ≤360 days after birth (first episode).

Exploratory:

Follow-up from birth to 180 days of age: PCR-confirmed RSV LRTD occurring ≤180 days after birth (first episode), stratified by: time from vaccination to birth, gestational age at vaccination, infant high-risk status for severe RSV, with/without administration with other vaccines during pregnancy.

PCR-confirmed RSV LRTD hospitalization occurring ≤180 days after birth (first episode), stratified by: time from vaccination to birth, gestational age at vaccination, infant high-risk status for severe RSV, with/without administration with other vaccines during pregnancy.

Follow-up from birth to 720 days of age: Among PCR-confirmed RSV-positive cases to ≤720 of age, describe timing, severity, sequelae, LRTD/LRTD hospitalization/acute otitis media (any cause) occurring ≤720 days after birth (total number of episodes).

Data analysis plan

RSV-specific infant analyses

RSV-specific from birth to ≤180 days of age through 6 months of age:

Outcomes among infants born to ABRYSVO-vaccinated and ABRYSVO-unvaccinated mothers will be compared using multivariable Cox proportional hazards regression models, generating aHR and 95% CI. IPTW derived from propensity scores may be considered, instead of conventional multivariable adjustment, to account for confounding bias. Calendar date will be used as the underlying time scale in the Cox models and VE will be calculated as (1 - aHR) and expressed as a percentage.

RSV-specific from birth to ≤360 days through 12 months of age:

This The analyses will stratify the Cox model by infant age; the exact width of discrete time intervals will be determined based on outcome incidence and ABRYSVO uptake.

RSV-specific from birth ≤720 days through 24 months of age:
Timing, severity, and sequelae will be described according to maternal ABRYSVO status. Among infants born to individuals who received ABRYSVO vaccine during pregnancy, we will describe the gestational age at ABRYSVO vaccination and the time interval from vaccination to birth.

Non-specific all-cause analyses
To be assessed for two overlapping follow-up periods: from birth to ≤180 days through 6 months of age and from birth to ≤720 days through 24 months of age.
All-cause analyses from birth to ≤180 days through 6 months of age:
Multivariable Cox proportional hazards regression models will be used to estimate VE. VE will be calculated as (1 - aHR) and expressed as a percentage.
All-cause analyses from birth to ≤720 days through 24 months of age:
Will be based on the total number of episodes of each outcome during follow-up. Poisson regression to generate aIRR for comparison. VE will be calculated as (1 - aIRR) and expressed as a percentage.

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 sources (types)

Electronic healthcare records (EHR)

Laboratory tests and analyses

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

No