Effectiveness of ABRYSVO® maternal respiratory syncytial virus (RSV) vaccine against RSV in infants in Western Pennsylvania (CASSATT)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000389

EU PAS number

EUPAS1000000389

Study ID

1000000389

DARWIN EU® study

No

Study countries

☐ United States

Study description

Globally, respiratory syncytial virus (RSV) is the leading cause of lower respiratory tract disease (LRTD) in infants. Pfizer has developed ABRYSVO—a bivalent RSV prefusion F protein-based vaccine (RSVpreF) composed of two prefusion F proteins to protect against both RSV-A and RSV-B.
In the United States, ABRYSVO has been approved and recommended for active immunization of pregnant individuals from 32 0/7 to 36 6/7 weeks' gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age.

To generate critical evidence to support vaccine policy and implementation, Pfizer will collaborate with University of Pittsburgh to study vaccine effectiveness (VE) of ABRYSVO vaccination during pregnancy against RSV-associated outcomes in infants. The study will take place in a real-world population in Western Pennsylvania over multiple seasons, beginning in the 2023-2024 season, and will use a test negative design (TND approach).
There will be no active enrollment of study participants, no direct contact with study participants, and no collection of any primary data outside of the Standard of Care (SOC).

This study will use a TND to evaluate real-world VE of maternal ABRYSVO against RSV-associated outcomes in infants. Additionally, we will describe RSV-associated medically-attended visits for infants exposed to ABRYSVO and Beyfortus (monoclonal antibody (MAB) administered to babies up to 24 months for protection against RSV).

Study status

Planned

Research institutions and networks

Institutions

University of Pittsburgh

Contact details

Study institution contact

Anne-Marie Rick

Study contact

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Primary lead investigator

Anne-Marie Rick

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/10/2024

Study start date

Planned: 24/02/2025

Date of interim report, if expected

Planned: 30/04/2025

Date of final study report

Planned: 20/12/2025

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

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This study uses UPMC electronic medical records to evaluate the real-world vaccine effectiveness of maternal ABRYSVO vaccination against RSV in infants and describes medically-attended visits for infants exposed to ABRYSVO and Beyfortus, with no active enrollment or direct participant contact.

Main study objective:

Estimate ABRYSVO VE against RSV positive acute respiratory illness (ARI) hospitalization among infants from birth through 3 months (0 through 90 days of age).

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Name of medicine

ABRYSVO

Anatomical Therapeutic Chemical (ATC) code

(J07BX05) respiratory syncytial virus vaccines

respiratory syncytial virus vaccines

Medical condition to be studied

Respiratory syncytial virus immunisation

Population studied

Short description of the study population

The study population will include infants who were hospitalized with ARI, have documented RSV test results and born to an individual eligible for ABRYSVO vaccination in pregnancy based on the timing of birth relative to the local seasonal ABRYSVO vaccination program.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Special population of interest

Pregnant women

Study design details

Setting

This health network-based retrospective study will be conducted using data from University of Pittsburgh Medical Center (UPMC), a semi-closed health network in Western Pennsylvania.

Two UPMC hospitals will be utilized to identify the source population in this study – UPMC Magee-Women's Hospital, which serves Pittsburgh, Pennsylvania and the surrounding area and has over 9,000 deliveries per year, and UPMC Hamot Hospital, which serves Erie, Pennsylvania and has over 3,000 deliveries per year. The integrated electronic health record at these hospitals allows for >95% of mothers and their infants to be linked within the EHR allowing for accurate characterization of maternal immunization. Furthermore, both hospitals participate in the Magee Obstetric Maternal & Infant (MOMI) Database, which collects over 300 maternal and infant variables from pregnancy, delivery, and postpartum for every pregnancy, allowing for standardized data collection for >95% of deliveries occurring in these hospitals.

The University of Pittsburgh and UPMC's bioinformatics group (R3) can routinely obtain structured data elements from the electronic health record including maternal and infant immunization records, laboratory results, medications, diagnosis codes, demographic and birth characteristics. Additional details of specific medical encounters, including details on reported clinical symptoms, vital signs, and physical exam findings, can be obtained using unstructured data abstraction with trained data abstractors, who enter data directly into electronic data collection tool. This detailed abstraction will allow for accurate characterization of viral infection that includes LRTD.

Outcomes

The outcome for the primary objective is RSV-positive ARI hospitalization confirmed by ≥1 acute respiratory illness symptom, laboratory testing, and hospitalization occurring 0 to ≤ 90 days of life during RSV season based on local epidemiology.

Outcomes for the secondary objective include:

- RSV-positive ARI hospitalization confirmed by ≥1 acute respiratory illness symptom, laboratory testing, and hospitalization occurring 0 to ≤ 180 days of life during RSV season based on local epidemiology.
- RSV -positive ARI hospitalization confirmed by ≥ 1 acute respiratory illness symptom, laboratory testing, and hospitalization occurring 90 to ≤180 days of life during the RSV season based on local epidemiology.
- RSV-positive ARI hospitalization with study-defined LRTD occurring 0 to ≤ 90 days of life during RSV season based on local epidemiology.
- RSV-positive hospitalization with study-defined LRTD occurring 0 to ≤180 days of life during RSV season based on local epidemiology.
- RSV-positive ARI hospitalization with study-defined LRTD occurring 90 to ≤ 180 days of life during RSV season based on local epidemiology.
- Number, age and characteristics of infants whose birth parent received ABRYSVO during pregnancy who present for a medical visit (outpatient, urgent care, emergency room, hospital) and have laboratory confirmed RSV between 0 to ≤ 90 days of life.
- Number, age and characteristics of infants who received Beyfortus between 0 to <7 days of life who present for a medical visit (outpatient, urgent care, emergency room, hospital) and have laboratory confirmed RSV between 1 to ≤ 90 days post-Beyfortus exposure.

The exploratory outcome is RSV-positive ARI hospitalization confirmed by ≥1 acute respiratory illness symptom, laboratory testing, and hospitalization occurring 0 to ≤30 days of life during RSV season based on local epidemiology.

Data analysis plan

For the TND study, baseline characteristics of the study population will be described by case/control status and by exposure status. A logistic regression model will be used to compute an odds ratio (OR), comparing the odds of maternal ABRYSVO vaccination during pregnancy between test-positive cases

and test-negative controls. From the OR, the VE will be calculated as (1−OR) x 100%. A multivariable logistic regression model will be used to compute an adjusted OR (aOR) from which we will derive final VE estimates, adjusted for potential confounding, according to the formula: VE = (1−aOR) x 100%. The same approach will be utilized for secondary and exploratory VE objectives.

For descriptive objectives, age at RSV+ medically attended visit as well as other descriptive characteristics such as demographics, co-morbid medical conditions, and location of medical visit will be described for infants exposed to ABRYSVO and Beyfortus.

Data management

Data sources

Data source(s), other

University of Pittsburgh Medical Center electronic health record data

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Data sources (types)

Electronic healthcare records (EHR)

Laboratory tests and analyses

Non-interventional study

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