Effectiveness and immunogenicity of respiratory syncytial virus vaccine (RSVpreF from Pfizer) for pregnant persons: A living systematic review and meta-analysis

First published: 30/09/2025

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000713

Study ID

1000000713

DARWIN EU® study

No

Study countries

Argentina

Study description

The study design is a Living Systematic Review (LSR) and meta-analysis to evaluate the effectiveness and immunogencity of RSVpreF maternal vaccine in infants and the effectiveness of the RSVpreF maternal vaccine in pregnant and postpartum individuals.
The study will follow the Cochrane and WHO methods, and the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA) statement.
The LSR was registered in the International Prospective Register of Systematic Reviews (PROSPERO) database under number CRD CRD420251077829, following the PRISMA-P statement.
The LSR and meta-analysis design was selected due to the ability to synthesize evidence continually, so the most recent, relevant and reliable evidence can be used to inform policy and practice.
All systematic reviews processes have been enhanced using the web-based powered by artificial intelligence (AI).

Study status

Ongoing

Research institutions and networks

Institutions

Instituto de Efectividad Clínica y Sanitaria A. Civil (IECS)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Dr. Mabel Berrueta

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/07/2025

Actual: 17/07/2025

Study start date

Planned: 30/09/2025

Actual: 30/09/2025

Data analysis start date

Planned: 01/12/2025

Date of final study report

Planned: 30/03/2028

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

C3671082

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:

The study design is a LSR and meta-analysis to evaluate the effectiveness and immunogencity of RSVpreF maternal vaccine in infants and the effectiveness of the RSVpreF maternal vaccine in pregnant and postpartum individuals.

Main study objective:

1. To evaluate the efficacy/effectiveness of maternal RSVpreF vaccination during pregnancy in preventing infants from RSV-specific and all-cause respiratory illness.
2. To evaluate the immune response associated with RSVpreF vaccination and how long it lasts in individuals vaccinated during pregnancy in the real-world.
3. To evaluate the efficacy/effectiveness of maternal RSVpreF vaccination during pregnancy in preventing maternal RSV-specific and all-cause respiratory illness.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Medicinal product name

ABRYSVO

Anatomical Therapeutic Chemical (ATC) code

(J07BX05) respiratory syncytial virus vaccines

respiratory syncytial virus vaccines

Medical condition to be studied

Respiratory syncytial virus infection

Population studied

Short description of the study population

Studies to be included will be those which evaluate immunogenicity and efficacy/effectiveness of RSVpreF vaccination of pregnant persons in pregnant and postpartum persons and their infants.
Eligible studies will include randomized and post-licensure observational studies reporting efficacy or effectiveness outcomes with sample sizes of at least 50 participants, and immunogenicity outcomes with at least 10 participants.

Age groups

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

Special population of interest

Nursing women

Pregnant women

Study design details

Setting

Studies to be included will be those which evaluate immunogenicity and efficacy/effectiveness of RSVpreF vaccination of pregnant persons in pregnant and postpartum persons and their infants.

Selected studies will include post-marketing observational and randomized studies reporting efficacy or effectiveness outcomes with sample sizes of at least 50 participants, and immunogenicity outcomes with at least 10 participants.

Outcomes

Outcomes included in the LSR will depend on the outcomes in published studies included. The following outcomes may be evaluated if data are sufficient, as well as other not specified outcomes.

Effectiveness outcomes: RSV detection, RSV acute respiratory illness [ARI, lower respiratory tract illness (LRTI) or disease (LRTD)] , RSV hospitalization, RSV LRTI/LRTD hospitalization, RSV complications including secondary bacterial infection, respiratory failure, multiorgan failure, death [including case fatality rate (CFR)], All-cause LRTI/LRTD, All-cause LRTI/LRTD hospitalization (does not require confirmation of etiology), Asymptomatic RSV infection , Antibiotic use in infants with RSV infection.

Immunogenicity outcomes: Humoral immune responses (quantity and durability) including RSV-A and RSV-B antibody titers and cellular immune responses, RSV viral load.

Data analysis plan

The final data set of pooled data is then summarized and mapped using PowerBI to create an interactive dashboard for data visualization, programmed by the IECS team and based on this protocol.

Meta-analyses will be performed using RShiny (RStudio language), incorporating random-effects models and proportional meta-analyses to

synthesize the data based on algorithms that select and automatically calculate the meta-analyses estimates.
Provided that data are available and methodologically suitable, aggregate meta-analyses will be performed for each comparison in accordance with the Cochrane Handbook of Systematic Reviews of Interventions, employing random-effects meta-analysis for primary analyses.
Proportional meta-analyses will be performed to summarize frequencies from 1-sample studies. R statistical software will be used to analyze the data. Hazard ratios, risk ratios, or odds ratios and corresponding 95% confidence intervals (CI) will be computed for dichotomous outcomes, whereas mean differences or standardized mean differences will be determined for continuous outcomes. Proportions with 95% CI will be determined for non-comparative studies. For reporting efficacy/effectiveness outcomes, measures will be converted into vaccine efficacy whenever feasible. Adjusted effect measures will be prioritized (e.g., by age, region, etc) over unadjusted estimates. Heterogeneity will be explored through subgroup analyses. Publication bias will be formally assessed by funnel plots and Egger and Begs tests. Sensitivity analysis will be undertaken by excluding high-risk bias studies.

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 data source

Data source(s), other

Cochrane Library databases,

MEDLINE, EMBASE,

Latin American and Caribbean Health Sciences Literature (LILACS),

Science Citation Index Expanded (SCI-EXPANDED),

China Network Knowledge Information (CNKI),

Chinese Biomedical Literature Database (CBM),

Chinese Science Journal Database (CSDC),

Grey literature published by national health agencies (e.g., US CDC, UKHSA) since August 2023 (date of RSVpreF maternal vaccine approval by the FDA) will also be included as data sources.

Data sources (types)

Published literature

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