Maternal Outcomes following RSVpreF Vaccination during prEgnancy (MORE)

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Study Planned

Administrative details

EU PAS number

EUPAS1000000923

Study ID

1000000923

DARWIN EU® study

No

Study countries

United States

Study description

This study will evaluate the availability of existing real-world data from Kaiser Permanente Southern California (KPSC) documenting the burden of RSV disease in pregnant and postpartum women. These findings are informative to future

investigations into the potential direct benefits of RSVpreF vaccination for pregnant and postpartum women.

This retrospective cohort study will use KPSC databases from October 2016 onward, with emphasis on September 2023 to the latest data when RSVpreF vaccine became available. The main cohort includes women aged 18–49 years with pregnancy records at KPSC. For exploratory purposes, a mother-infant sub-cohort of postpartum women with linked infant health records and confirmed RSV infection in children under one year will be created. ARI and LRTD episodes within this group will help assess under-ascertainment of RSV-related respiratory infections in postpartum women.

Study status

Planned

Research institutions and networks

Institutions

Kaiser Permanente Southern California (KPSC)

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Institution

Contact details

Study institution contact

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Primary lead investigator

Annette Regan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/01/2026

Actual: 29/01/2026

Study start date

Planned: 30/06/2026

Data analysis start date

Planned: 01/07/2026

Date of final study report

Planned: 31/03/2027

Sources of funding

- Pharmaceutical company and other private sector

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:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Feasibility analysis

Data collection methods:

Secondary use of data

Study design:

This retrospective study uses KPSC data from 2016 onward to examine RSV trends across pre-pandemic, pandemic, and post-RSVpreF vaccine periods,

focusing on pregnant women aged 18–49 and an exploratory mother-infant sub-cohort to assess RSV-related respiratory illness, potential under-ascertainment.

Main study objective:
To describe the frequency and proportion of RSV-associated LRTD among pregnant and postpartum women.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Medicinal product name
ABRYSVO

Population studied

Short description of the study population
The Southern California Permanente Medical Group serves over 4.9 million members through 202 clinics and 16 hospitals in Southern California, offering hospital, outpatient, emergency, urgent, and home care services to a highly diverse population. The primary study cohort includes pregnant or postpartum women (aged 18–49) with live or stillbirths at ≥20 weeks gestation. A maternal-infant sub-cohort includes women from this group with a linked infant record for exploratory analysis.

Age groups

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

Special population of interest

Immunocompromised

Pregnant women

Estimated number of subjects

50000

Study design details

Setting

Southern California Permanente Medical Group is one of the largest medical groups in the U.S., including over 4.9 million members.

Outcomes

RSV-LRTD will be identified using ICD-10-CM diagnostic codes in conjunction with laboratory testing performed at both outpatient and inpatient settings during the study period.

Data analysis plan

The analyses encompass a thorough description of the study population’s characteristics, providing essential context for understanding the results. Additionally, the study includes descriptive analyses of laboratory testing for RSV among pregnant and postpartum women who have been clinically diagnosed with LRTD and ARI.

Further, the frequency and proportion of RSV-associated LRTD and RSV-associated ARI among pregnant and postpartum women are examined to better characterize the burden of disease in this population. The analyses also involve calculating the rate of laboratory testing for RSV in pregnant and postpartum people diagnosed with LRTD or ARI.

Finally, the study calculates the rates of ARI and LRTD among pregnant and postpartum women who have an infant with evidence of a recent RSV illness, providing insight into potential patterns or associations between maternal and infant health outcomes.

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

Existing electronic health records from the KPSC healthcare system; California State Automated Vital Statistics System (AVSS), California Immunization Registry (CAIR)

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Vaccination 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