STudy of Real world vaccinE Effectiveness of maTernal RSVpreF vaccinatiON against respiratory syncytial virus (RSV) in hospitalised infants in Australia (STREETON)

First published: 21/07/2025

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000598

Study ID

1000000598

DARWIN EU® study

No

Study countries

Australia

Study description

This Pfizer-sponsored real-world retrospective non-interventional (NI) study will be conducted within a research network comprised of independent hospitals across Australia using data collected during routine standard of care (SOC) clinical encounters available in health records (including both digital and/or paper records), supplemented with information from the official national immunisation registry, the Australian Immunisation Register (AIR). Additional data from accredited pathology laboratories will be included.
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 SOC.
This study will use a test negative design (TND) to evaluate real-world vaccine effectiveness (VE) of ABRYSVO vaccination during pregnancy against RSV-associated outcomes in infants.

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

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Study timelines

Date when funding contract was signed
Planned: 01/07/2025

Actual: 30/06/2025

Study start date
Planned: 11/08/2025

Actual: 11/08/2025

Date of final study report
Planned: 30/07/2027

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

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 retrospective NI study will be conducted within a research network comprised of independent hospitals across Australia using data collected during routine
SOC clinical encounters available in health records,
supplemented with information from the official national immunisation registry, AIR.

Main study objective:

Primary Research Question: What is the real-world effectiveness of ABRYSVO vaccination during pregnancy against respiratory syncytial virus (RSV)-associated outcomes in infants in Australia?

Primary Research Objective: The primary objective is to estimate vaccine effectiveness (VE) of ABRYSVO during pregnancy against RSV-positive lower respiratory tract disease (LRTD) hospitalisation among infants from birth through 6 months (0 to ≤180 days) of age using a case-control study with a test negative design (TND).

Study drug and medical condition

Medicinal product name

ABRYSVO

Population studied

Short description of the study population

Inclusion Criteria:

Participants must meet all of the following inclusion criteria to be eligible for inclusion in the

study:

1. Infant ≤12 months (≤360 days) of age on the hospitalisation date.

2. Index date within the time period for data collection (approximately 01 March 2025 –

28 February 2027; Refer to Section 9.1.).

3. Hospitalised with ARI meeting the protocol-defined clinical case definition, and for whom RSV testing results from a specimen collected 10 days prior to hospital admission through 3 days after a hospital admission are known. See Section 9.3.2. for ARI hospitalisation definition.

4. Infant date of birth on or after 17 February 2025 (≥14 days after start of the first national ABRYSVO vaccination campaign to ensure potential to have been born to an ABRYSVO-vaccinated mother).

5. Infant born to a birth mother eligible to receive ABRYSVO vaccination *h

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*h: Birth mothers who were expected (based on estimated date of delivery) to reach ≥28 ⁰⁄₇ wGA on or after

03 February 2025.

Exclusion Criteria

Participants meeting any of the following criteria will not be included in the study:

1. Infant born at <28⅐ weeks of gestational age.
1. Infant received any licensed or investigational RSV preventive product (e.g., palivizumab, nirsevimab, active RSV vaccine) since birth.
2. Infant received ≥1 blood transfusion or other blood products containing antibody (e.g., fresh frozen plasma) since birth.
3. Infant born to a birth mother who received any other licensed or investigational RSV vaccine during this pregnancy.
4. Infant born to a birth mother for whom ABRYSVO vaccination status cannot be confirmed in available data sources.

Study design details

Setting

This hospital-based retrospective study will be conducted in a research network of up to 9 independent hospitals across 6 states/territories in Australia. A list of each hospital, with accompanying details, will be provided in the statistical analysis plan (SAP).

Given the retrospective nature of this study, hospitals that already function as national sentinel units for respiratory virus surveillance, or that have robust clinical, laboratory or epidemiological surveillance will be included. Each participating hospital conducts year-round SOC testing for ARI which includes respiratory virus panel test using polymerase chain reaction (PCR).

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)

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

No