Evaluating the benefits of RSV maternal vaccination using a Scottish National Dataset. (BORLAND)

First published: 07/10/2025

Last updated: 24/11/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000000706

Study ID

1000000706

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This study will use a retrospective cohort design and will be conducted within routinely collected national healthcare and statutory demographic datasets held by Public Health Scotland (PHS) and National Records of Scotland (NRS). As such, there will be no active enrolment of study participants, no direct contact with study participants, no collection of any primary data outside of the standard of care (SOC), and no requirement for informed consent.
Study outcomes among infants born to ABRYSVO-vaccinated mothers (exposed group) will be compared with those among infants born to ABRYSVO-unvaccinated mothers (comparison group) initially from birth through 6 months of age, with later analysis from birth through 12 months as the infants reach this age threshold and their data become available.

This will be a whole population birth cohort study of all live-born infants born in Scotland during the study period. In Scotland, all infants are assigned a unique identifier, the Community Health Index (CHI) at birth. CHI is a common identifier across all National Health Service (NHS) healthcare encounters and allows linkage of all healthcare data to statutory datasets such as death records. The patient population will include all live-born infants born in Scotland over an 18-month accrual period, from 01 September 2024 – 01 February 2026 (end of respiratory syncytial virus (RSV) season) with a gestational age at birth ≥280/7 weeks of gestation and their mothers (approximately 69,000 mother-infant pairs).
Selection criteria for the population were based on the time period of the RSV season in Scotland and the earliest gestational age eligible for ABRYSVO vaccination, per the Medical and Healthcare Products Regulatory Agency (MHRA). All infants will be followed for 12 months after birth; thus, the last outcome assessment will be approximately 01 February 2027.

Study status

Planned

Research institutions and networks

Institutions

University of Glasgow

Contact details

Study institution contact

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Study contact

louisa.pollock@glasgow.ac.uk

Primary lead investigator

Louisa Pollock

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/06/2025

Actual: 12/06/2025

Study start date

Planned: 11/12/2026

Date of final study report

Planned: 30/06/2027

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

C3671083, BORLAND

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 is a retrospective cohort design that will be conducted within routinely collected national healthcare and statutory demographic datasets held by PHS and National Records of Scotland (NRS).

Main study objective:

To estimate the vaccine effectiveness (VE) of ABRYSVO vaccination during pregnancy against polymerase chain reaction (PCR)-confirmed RSV-associated lower respiratory tract disease (LRTD) hospitalisation among infants from birth through 6 months of age.

Study Design

Non-interventional study design

Cohort

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

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The patient population will include all live-born infants born in Scotland over an 18-month accrual period, from 01 September 2024 – 01 February 2026 (end of RSV season) with a gestational age at birth ≥280/7 weeks of gestation, and their mothers (approximately 69,000 mother-infant pairs).

Selection criteria for the population were based on the time period of the RSV season in Scotland and the earliest gestational age eligible for ABRYSVO vaccination, per the MHRA.

All infants will be followed for 12 months after birth; thus, the last outcome assessment will be approximately 01 February 2027.

Age groups

- Neonate
  - Preterm newborn infants (0 – 27 days)
  - Term newborn infants (0 – 27 days)

- Infants and toddlers (28 days – 23 months)

Study design details

Setting

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The patient population will include all live-born infants born in Scotland over an 18-month accrual period, from 01 September 2024 – 01 February 2026 (end of RSV season) and their mothers (approximately 69,000 mother-infant pairs). Selection criteria for the population were based on the time period of the RSV season in Scotland and the earliest gestational age eligible for ABRYSVO vaccination, per the MHRA. All infants will be followed for 12 months after birth; thus, the last outcome assessment will be approximately 01 February 2027.

Outcomes

All RSV-specific infant outcomes will be based on a positive PCR test and will be assessed year-round, during both the RSV season and off-season. PHS surveillance data will be used to determine RSV seasonal periods.

RSV-specific outcomes will include:

• PCR-confirmed RSV-associated LRTD hospitalisation

• PCR-confirmed RSV-associated hospitalisation

Identification of RSV-specific outcomes will be based on the first positive PCR test from Electronic Communication of Surveillance Scotland (ECOSS), occurring

during the relevant follow-up period.
All-cause outcomes will include:

All-cause LRTD hospitalization:
Identification of all-cause LRTD hospitalization will be based on ICD-10-CM diagnostic codes documented in infant admissions data (SMR01) during hospital admissions for infants from birth through 12 months of age (0 to ≤360 days).

Data analysis plan

• Descriptive population and vaccination analysis: Baseline characteristics of mothers and infants, as well as vaccination timing and intervals, will be summarized using frequencies for categorical variables and summary statistics for continuous variables, stratified by ABRYSVO vaccination status.
• RSV-specific infant outcome analysis: Incidence rates for RSV-associated outcomes will be calculated overall and by vaccination status, with follow-up from birth through 6 and 12 months. Adjusted hazard ratios from inverse probability of treatment weights (IPTW) weighted Cox regression models will be used to estimate vaccine effectiveness (VE), accounting for confounders.
• All-cause infant outcome analysis: Hospitalisations for all-cause acute respiratory infections and lower respiratory tract disease will be analyzed similarly through 12 months, using first-episode and total-episode approaches with weighted IPTW Poisson regression to estimate adjusted incidence rate ratios and VE.
• Exploratory subgroup and hospitalisation characteristics: Characteristics of RSV hospitalisations and potential predictors of breakthrough RSV hospitalisation among vaccinated infants will be examined using descriptive statistics and regression models, with attention to sample size limitations and privacy rules for small counts.

Data management

Data sources

Data source(s)

Other data source

Data source(s), other

SLiPBD – Scottish Linked Pregnancy and Baby Dataset

PHS Child Health Dataset

SMR01 – NHS hospital admissions data

ECOSS – Electronic Communication of Surveillance Scotland (respiratory virus testing results)

CHI database – Community Health Index (patient identifier and transfer tracking)

PHS vaccination data

NRS – National Records of Scotland (birth and death data)

SMR02 - Scottish Morbidity Record 02 (maternity admissions data)

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