Effectiveness and Impact of Nirsevimab on medium to long-term RSV associated outcomes in Finland – Population-based registry study (RSV506)

First published: 11/08/2026

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Study Planned

Administrative details

EU PAS number

EUPAS1000001045

Study ID

1000001045

DARWIN EU® study

No

Study countries

Finland

Study description

Respiratory syncytial virus (RSV) causes substantial respiratory disease burden in infants, and nirsevimab was introduced in Finland in 2024 to prevent RSV disease during the first RSV season. This population-based nationwide register study evaluates the real-world effectiveness and impact of universal nirsevimab immunoprophylaxis in Finland. The primary cohort includes infants eligible for nirsevimab during the 2024–2025 RSV season. Effectiveness will be assessed by comparing immunized and non-immunized eligible infants. Population impact will be assessed using before–after comparisons with historical birth cohorts. Outcomes include RSV-related respiratory disease, antibiotic use, otitis media, recurrent wheezing, and asthma. Individual-level national register data will be linked using personal identity codes.

Study status

Planned

Research institutions and networks

Institutions

FVR – Finnish Vaccine Research

Finland

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Institution **Hospital/Clinic/Other health care facility**

Laboratory/Research/Testing facility

Contact details

Study institution contact

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 15/09/2025

Study start date

Planned: 02/07/2026

Date of final study report

Planned: 31/12/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi Winthrop Industrie

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

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

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

NIRSEVIMAB

Medical condition to be studied

Asthma

Population studied

Short description of the study population

All children born and residing in Finland who were eligible for nirsevimab immunoprophylaxis during the 2024–2025 RSV season. The primary study cohort includes infants born between 1 August 2024 and 30 March 2025.

Age groups

- Neonate
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)

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

Finnish health registers

Statistics Finland's datasets

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