Effectiveness and impact of a 2-component acellular pertussis vaccine as a preschool booster in Finland – A register-based study (PER000108)

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000107

Study ID

1000000107

DARWIN EU® study

No

Study countries

Finland

Study description

This is a nationwide population-based register study on pertussis in children less than 14 years of age in 1995-2019. We will estimate the effectiveness of preschool pertussis vaccination in a cohort design, by previos vaccination status and by time since vaccination, and assess its impact by comparing vaccination programs with and without preschool vaccination. In addition, we will assess the patterns of pertussis by age, time, area, vaccination status and hospitalization.

Study status

Ongoing

Research institutions and networks

Institutions

FVR – Finnish Vaccine Research

Finland

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Last updated: 15/11/2024

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

Laboratory/Research/Testing facility

Contact details

Study institution contact

Ritva Syrjänen ritva.syrjanen@fvr.fi

Study contact

ritva.syrjanen@fvr.fi

Primary lead investigator

Arto Palmu

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 26/04/2023

Study start date
Actual: 03/07/2023

Data analysis start date
Planned: 30/06/2024

Date of final study report
Planned: 30/06/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi Pasteur S.A.

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

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Cohort study for estimating effectiveness, before-after comparison to compare different vaccination programs, descriptive epidemiology

Main study objective:

To evaluate the direct effectiveness of a 2-component acellular pertussis (2aP) vaccine administered as a preschool booster at 4 years of age against laboratory-confirmed pertussis during a follow-up of 5 years.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Before-after comparison

Study drug and medical condition

Medicinal product name, other

Pertussis vaccine

Medical condition to be studied

Pertussis

Pertussis immunisation

Population studied

Short description of the study population

Children less than 14 years of age in Finland 1995-2019, based on nationwide registers and population data

Estimated number of subjects

2.500.000

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 nationwide registers

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug registry

Population 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