ADVANCE POC Study Protocol - Testing new approaches to monitoring benefit/risk with pertussis vaccines as test case. Coverage rates of acellular and whole-cell pertussis-containing vaccines in preschool children (ADVANCE Coverage POC)

First published: 29/06/2016

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS13908

Study ID

21742

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Italy
- ☐ Spain
- ☐ United Kingdom

Study description

The overall ADVANCE proof-of-concept (POC) question is to test the system for benefit-risk monitoring of vaccines in Europe. This will first be done by using test cases. For this POC, the following research question is used: “Has the initial benefit-risk profile in children prior to school-entry booster been maintained after the switch from whole-cell pertussis vaccines to acellular pertussis vaccines”?

Study status

Finalised

Research institutions and networks

Institutions

Department of Epidemiology Research, Statens Serum Institut

☐ Denmark

First published: 16/03/2010

Last updated: 24/02/2012

Institution | EU Institution/Body/Agency | Laboratory/Research/Testing facility | ENCePP partner

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/05/2025

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

THIN UK, FISABIO Spain, BIFAP spain, SSI Denmark

Networks

Accelerated development of vaccine benefit-risk collaboration in Europe (ADVANCE)

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Hanne-Dorthe Emborg

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/10/2013

Actual: 01/10/2013

Study start date
Planned: 01/06/2016

Actual: 01/06/2016

Date of final study report
Planned: 15/09/2016

Actual: 29/06/2016

Sources of funding

- EU institutional research programme
- Pharmaceutical company and other private sector

More details on funding

GSK, SP, NOVARTIS, SP MSD, CRUCELL, PFIZER, TAKEDA, IMI

Study protocol

ADVANCE POC-Coverage-Protocol.pdf(1.62 MB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Coverage study

Data collection methods:

Secondary use of data

Main study objective:

To estimate the coverage of pertussis-containing vaccines in children less than 6 years of age. The specific objective of this study is to assess the system capability to estimate acellular pertussis and whole-cell pertussis vaccine coverage

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective population based cohort study

Study drug and medical condition

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

PERTUSSIS VACCINE

Population studied

Short description of the study population

All children registered in any of the participating databases during the study period and for whom an adequate start and end of follow-up and date of birth can be defined.

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Estimated number of subjects

10000000

Study design details

Outcomes

Coverage rate overall and for wP and aP vaccines is the proportion of vaccinated children by database, birth cohort, age in months and per dose The variability of vaccine administration is defined as the time elapsed between birth and the first dose and the time elapsed between subsequent scheduled doses.Changes of coverage rates over time will be described by general descriptive statistic

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Data analysis plan

• The coverage by age in months per birth cohort will be calculated using a Kaplan-Meier method. The proportion of vaccinated children with dose 1, 2, 3, and subsequent boosters will be calculated stratified by year of birth, type of vaccine and database.• The change of coverage rates over time will be calculated by the difference between coverage rates and a defined threshold. Low coverage thresholds will be determined for identification of variability of interest/concern. Data-driven thresholds will be compared with set values based on coverage rates required for herd immunity. CUSUM involves the calculation of a cumulative sum (which is what makes it ‘sequential’). It is designed to detect changes in the difference. It differs from Sequential Probability Ratio Test (SPRT) by always using zero function as the lower ‘holding barrier’. Also, CUSUM does not require the use of the likelihood function.

Documents

Study results

EUPAS13908-21740.pdf(813.13 KB)

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

The Information System for Research in Primary Care (SIDIAP)

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

ARS Toscana

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

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