Testing new approaches to monitoring benefit/risk with pertussis vaccines as test case: Incidence rates of pertussis and pertussis related outcomes of whole-cell pertussis and acellular pertussis vaccines in pre-school children (benefit study on pertussis vaccination)

First published: 10/06/2016

Last updated: 01/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/21757

EU PAS number

EUPAS13766

Study ID

21757

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Italy
- ☐ Netherlands
- ☐ Spain
- ☐ Sweden

Study description

The overall 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”?There will we 3 different POCs carried out, the one presented here will test the benefits of pertussis vaccines in the population.

Study status

Finalised

Research institutions and networks

Institutions

P95 Clinical and Epidemiology Services

- ☐ Belgium

- [ ] Colombia
- [ ] Netherlands
- [ ] South Africa
- [ ] Thailand
- [ ] United States

First published: 07/11/2022

Last updated: 21/02/2025

Institution | Laboratory/Research/Testing facility | Non-Pharmaceutical company | ENCePP partner

VACCINE.GRID

- [ ] Switzerland

First published: 26/06/2012

Last updated: 20/08/2024

Institution | Not-for-profit

University Medical Center Utrecht (UMCU)

- [ ] Netherlands

First published: 24/11/2021

Last updated: 22/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care 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

P95 Clinical and Epidemiology Services

- [ ] Belgium
- [ ] Colombia
- [ ] Netherlands
- [ ] South Africa
- [ ] Thailand
- [ ] United States

First published: 07/11/2022

Last updated: 21/02/2025

Institution | Laboratory/Research/Testing facility | Non-Pharmaceutical company | 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: 23/02/2024

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

Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency for Medicines and Medical Devices, AEMPS)

Spain

First published: 01/02/2024

Last updated: 04/09/2024

Institution | EU Institution/Body/Agency | Not-for-profit | Regulatory Authority | ENCePP partner

IMS Health

First published: 01/02/2024

Last updated: 01/02/2024

Institution

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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Primary lead investigator

Miriam Sturkenboom

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/10/2013

Actual: 31/10/2013

Study start date
Planned: 02/04/2016

Actual: 01/10/2016

Date of final study report
Planned: 31/10/2016

Actual: 30/07/2017

Sources of funding

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

More details on funding

Sanofi Pasteur, GSK, MSD Sanofi Pasteur, IMI

Study protocol

pertussis_benefit_POC.pdf(1.96 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 type list

Study topic:

Disease /health condition

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The objective of the work of the benefit pillar is to calculate incidence rates that will feed into the benefit/risk model (benefit-risk protocol).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Pertussis

Seizure

Death

Pneumonia bacterial

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

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Estimated number of subjects

30000000

Study design details

Outcomes

pertussis is the primary outcome, Secondary outcomes are complications to pertussis, such as pneumonia and seizure and death.

Data analysis plan

The incidence rate of each event will be calculated using a dynamic cohort approach. When analyzing the incidence of pertussis, for each person in the cohort, follow-up time will be classified by calendar year, sex, age in months and the different risk window (see exposure section). This persontime will be the denominator for the incidence rate calculations. Incidence rates for the different outcomes will be calculated stratified by:1. database2. calendar year and month3. age in categories4. vaccination status by risk window stated above5. pertussis prior to first dose

Documents

Study results

EUPAS13766-21754.pdf(266.57 KB)

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Integrated Primary Care Information (IPCI)

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

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection

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