Immune thrombocytopenia following vaccination with DTaP-IPV or TdaP-IPV in children

First published: 16/06/2023

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS104290

Study ID

104291

DARWIN EU® study

No

Study countries

France

Germany

United Kingdom

Study description

A cohort study to generate estimates on the use of combined diphtheria / tetanus / pertussis (acellular, component) / poliomyelitis (inactivated) vaccines (DTaP-IPV or TdaP-IPV) in the general population, and incidence rates for of immune thrombocytopenia in the general population and in the population exposed to the above vaccines, across three European databases

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Robert Flynn

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 04/07/2022

Actual: 04/07/2022

Study start date
Planned: 04/07/2022

Actual: 04/07/2022

Date of final study report
Planned: 02/09/2022

Actual: 07/09/2022

Sources of funding

- EMA

Study protocol

Analysis Plan_Immune thrompocitopenia 202207_for publication_CLEAN.pdf

(815.96 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

Describe: • How the diphtheria / tetanus / pertussis (acellular, component) / poliomyelitis (inactivated) vaccines (DTaP-IPV or TdaP-IPV) were used in the general population? • How has use of the vaccine changed with time? • What was the event rate of immune thrombocytopenia in the general population? • What was the event rate in the population exposed to the vaccine?

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07CA02) diphtheria-pertussis-poliomyelitis-tetanus

diphtheria-pertussis-poliomyelitis-tetanus

Medical condition to be studied

Thrombocytopenia

Thrombocytopenic purpura

Population studied

Short description of the study population

The study population included general population and patients visiting general practices identified from the IMRD databases.

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days – 23 months)
- Term newborn infants (0 – 27 days)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

200000

Study design details

Data analysis plan

A cohort study describing vaccine exposure, population incidence rates of immune thrombocytopenia, and (where possible) incidence rates of immune thrombocytopenia in the vaccine exposed population. Vaccine exposure was described as counts of patients with a first exposure stratified by age, sex, and year of general practice visit. Incidence of new onset immune thrombocytopenia in all patients contributing patient time to the databases, excluding those with any prior history of any of the selected codes for thrombocytopenia in the database, and then restricting to only those patients known to have been exposed to the vaccine. Follow up time (years) = ((end date for the period – start date for the period + 1))/365, Incidence rate = (number of new onset events)/(total follow up time (years)). Incidence is presented as the number of events per 100,000 person-years, calculated for the

entire population as well as stratified by year, gender, and age group.

Documents

Study results

FINAL Report_Immune thrombocytopenia_20220909_for publication_CLEAN.pdf (2.4 MB)

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)

IQVIA Disease Analyzer Germany

Disease Analyzer - OMOP

Data sources (types)

Drug dispensing/prescription data

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

No