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

First published: 16/06/2023

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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/104291

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 institution and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

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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 data collection

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

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
Term newborn infants (0 – 27 days)
Infants and toddlers (28 days – 23 months)
Children (2 to < 12 years)
Adolescents (12 to < 18 years)
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

Data sources

Data source(s)
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