Evaluation of vaccination error cases with fatal outcome reported to EudraVigilance

First published: 15/08/2018
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Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/27849

EU PAS number
EUPAS25265

Study ID
27849

DARWIN EU® study
No

Study countries
Netherlands

Study description
This study will be a case-series analysis with the aim to review ICSRs reporting vaccination errors with fatal outcome as reported in EudraVigilance. Causality of the vaccine with regards to the fatal outcome will be assessed using the WHO tool for causality assessment of AEFI. The case review will be performed by two independent reviewers, who will also estimate the contribution of the vaccination error to the fatal outcome.

Study status
Planned

Research institution and networks

Institutions

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

Netherlands
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02/05/2024

Institution

Educational Institution

ENCePP partner

Medicines Evaluation Board Utrecht, Netherlands

Contact details

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Study contact

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Primary lead investigator
Christina Hoeve

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
01/12/2015

Study start date
Planned:
01/01/2001

Date of final study report
Planned:

30/06/2019

Sources of funding

- Other

More details on funding

Erasmus Medical Center

Study protocol

Study protocol_Fatal vaccination errors_v3.2_20180815.pdf(673.3 KB)

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 type:
Non-interventional study

Scope of the study:
Other

If ‘other’, further details on the scope of the study
Case review of spontaneous reporting data

Main study objective:

This study aims to review cases in Eudravigilance between 1 January 2001 and 31 December 2016 reporting vaccination errors with fatal outcome.

Study Design

Non-interventional study design
Other

Non-interventional study design, other
Case-series

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(J07A) BACTERIAL VACCINES
(J07B) VIRAL VACCINES
(J07C) BACTERIAL AND VIRAL VACCINES, COMBINED

Population studied

Age groups
Preterm newborn infants (0 – 27 days)
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
0

Study design details

Outcomes
Death

Data analysis plan
Cases are identified from EudraVigilance using the Standard MedDRA Query for medication errors in combination with a reported vaccine and a fatal outcome. All cases received between 1 January 2001 and 31 December 2016 are included for the analysis. A causality assessement for death will be performed by two independednt reviewers using the AEFI causality assessment form of the WHO and an estimation of the impact of the error will be performed.

Data management

Data sources

Data source(s), other
EudraVigilance

Data sources (types)
Spontaneous reporting system

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