Evaluation of vaccination error cases with fatal outcome reported to EudraVigilance

First published: 15/08/2018

Last updated: 02/02/2019

Study Planned

Administrative details

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 institutions and networks

Institutions

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

Netherlands

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Institution **Educational Institution** **ENCePP partner**

Medicines Evaluation Board Utrecht, Netherlands

Contact details

Study institution contact

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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

BACTERIAL VACCINES

(J07B) VIRAL VACCINES

VIRAL VACCINES

(J07C) BACTERIAL AND VIRAL VACCINES, COMBINED

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

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), other

EudraVigilance

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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