Evaluation of vaccination error cases with fatal outcome reported to EudraVigilance

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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

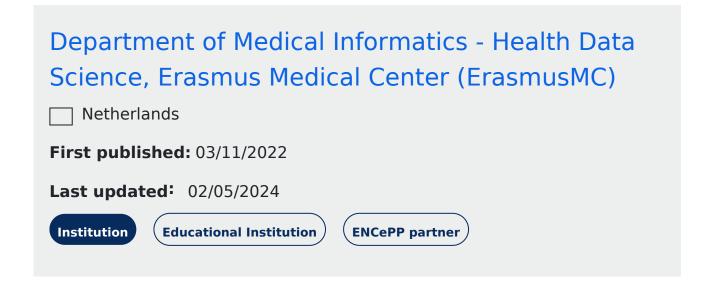
tool for causality assessment of AEFI. The case review will be performed by two independent reviewers, who will also estimate the contribution of the vaccination error to the fatal outcome.

Study status

Planned

Research institutions and networks

Institutions



Medicines Evaluation Board Utrecht, Netherlands

Contact details

Study institution contact

Christina Hoeve c.hoeve@erasmusmc.nl

Study contact

c.hoeve@erasmusmc.nl

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

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)

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 a	adverse drug reactions
Use of a Common Dat	a Model (CDM)
CDM mapping	
No	
Data quality specificat	tions
Check conformance	
Unknown	
Check completeness	
Unknown	
Check stability	
Unknown	
Check logical consistency	
Unknown	

Data characterisation

Data characterisation conducted

No