Surveillance of Adverse Event related to childhood vaccination reported by parents

First published: 29/05/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5350

Study ID

28000

DARWIN EU® study

No

Study countries

☐ Italy

Study description

Background: In recent years in Italy the trend of spontaneous reports of suspected adverse reactions from vaccine has been influenced by several factors. In 2009 there was an increase in reporting linked to the pandemic

influenza vaccine, while in 2011-2012 many reports are linked to the active post licensure safety monitoring of HPV vaccine. The new Pharmacovigilance legislation came into force in Europe in July 2012 and one of the indication was to increase the involvement of patients in reporting systems. Objective: the surveillance of adverse event after immunization (AEFI) reported by patients. Methods: Every adverse event should be reported immediately to healthcare professional in the vaccination center. The safety of vaccines is linked to the constant surveillance of adverse events. In this study all vaccinated children until to 15 months age were involved. For each vaccination parents will receive a Vaccination Diary for surveillance of adverse events by the healthcare professional, accompanied by a letter describing this project and reminding the importance of reporting. First of all healthcare professional will complete the Vaccination Diary in the vaccine section and then the parents should complete the Vaccination Diary describing any adverse event occurred after administration of vaccine. This Vaccination Diary may be delivered to next vaccination or sent by fax or e-mail, even if parents don’t observe any adverse event. This pilot study lasts three months from 1th October/November 2013 until 31st December/January 2013. All Vaccination Diaries delivered by parents will be collected and sent to the Regional Centre of Pharmacovigilance. These diaries with an adverse events will be included in the Italian Pharmacovigilance database.

Study status

Finalised

Research institutions and networks

Institutions

Pharmacology Unit - Veneto Pharmacovigilance Centre (Pharmacol UNIVR), University Hospital Verona

Italy

First published: 25/10/2022

Last updated: 13/03/2025

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Department of Biomedical and Dental Sciences and Morphofunctional Imaging, University of Messina

Italy

First published: 29/11/2021

Last updated: 20/08/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

One local health unit Veneto Region, One local health unit Liguria Region, One local health unit Emilia -Romagna Region, Three local health units Piemonte Region, Nine local health units Sicily

Region, One local health unit Calabria Region,

Three local macro-areas Autonomy Trento Region

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Moretti Ugo

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2011

Actual: 01/01/2011

Study start date

Planned: 01/01/2012

Actual: 01/01/2012

Data analysis start date

Planned: 01/05/2014

Actual: 01/05/2014

Date of final study report
Planned: 01/10/2014

Actual: 09/02/2015

Sources of funding

- Other

More details on funding

Italian Agency Medicines

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

To involve parents in the spontaneuos reporting system of Adverse Event following immunization (AEFI). Therefore to propose a routinary procedure in the local health units.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Intensive monitoring schemes

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07) VACCINES

VACCINES

Population studied

Short description of the study population

Vaccinated children until to 15 months age.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Estimated number of subjects

42000

Study design details

Outcomes

increase of reporting rate of vaccines

Data analysis plan

All AEFI reports will be introduced in the Italian Pharmacovigilance Database. All data will be evaluated in order to find potential signals.Reports from parents will be compared with reports from health operators

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 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

Unknown