201889 - Planned analyses related to the Post-Authorization Safety Study (PASS) of Post-Marketing Surveillance for Intussusception following Rotarix introduction into the Instituto Mexicano del Seguro Social (IMSS) in Mexico.

First published: 31/03/2014

Last updated: 01/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/31674

EU PAS number

EUPAS6110

Study ID

31674

DARWIN EU® study

No

Study countries

☐ Belgium

Study description

The aim of these planned analyses linked to Post-Authorization Safety Study (PASS) was to assess the risk of Intussusception after the 1st and the 2nd dose of Rotarix and Rotateq vaccines and provide an overall estimate of the risk after each dose by combining results from different studies using meta-analysis method.Please refer also to the summary of the initial PASS study, submitted to this registry as a separate study entitled "Post-Authorization Safety Study (PASS) of Post-Marketing Surveillance for Intussusception Following Rotarix Introduction into the Instituto Mexicano del Seguro Social (IMSS) in Mexico".

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact

Call Center EU Clinical Trials

Study contact

Vx.publicdisclosureglobal@gsk.com

Primary lead investigator

Call Center EU Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/06/2013

Study start date

Actual: 08/06/2013

Date of final study report

Actual: 05/07/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline Biologicals

Study protocol

104435-Additional-analysis-redact.pdf(437.17 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

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

Data collection methods:

Secondary use of data

Main study objective:

To provide a single estimate of the relative risk of IS after the 1st and the 2d dose of Rotarix.To provide a single estimate of the relative risk of IS after the 1st and the 2d dose of Rotateq.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Name of medicine

ROTARIX

ROTATEQ

Medical condition to be studied

Intussusception

Population studied

Short description of the study population

Subjects (more than 6 weeks of age) vaccinated with Rotarix and Rotateq vaccines.

Age groups

Infants and toddlers (28 days – 23 months)

Estimated number of subjects

1

Study design details

Outcomes

Relative risk of Intussusception (IS) following the 1st and the 2nd dose of Rotarix and Rotateq vaccines during the 7 days (Day 0 - Day 6) after vaccination.

Data analysis plan

Two analyses were done- Main analysis including the 6 above-referred publications,- A sensitivity analysis including in addition, Weinstrub et al. 2014.Studies which met the following criteria were included in the main analysis:- Post-marketing studies (no clinical trials),- Risk estimated for the 7-day period after vaccination,- Risk estimated for dose 1 and dose 2, separately,- Data obtained through active and/or passive surveillance on “confirmed” IS cases (Brighton or other method of case adjudication),- Full report or publication available.There was one sensitivity analysis conducted:- Analysis included only SCCS, SCRI and case-control designs.The analyses were done using the risk estimates and its 95% confidence intervals (CI) reported in the publications or reports. No raw data were used.Analyses were done separately for Rotarix and Rotateq.

Documents

Study results

104435-SAR E01_16-V1.pdf(643.97 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Meta-analysis on the following published studies:Carlin JB, et al. 2013 Clin Infect Dis,57:1427-34.Haber P. et al. 2013 Pediatrics 131, 1042-1049.Patel M et al 2011 N Engl J Med 364, 2283-2292. Shui I.M. et al. 2012 JAMA 307, 598-604.Velázquez et al. (2012) PIDJ 31, 736-744.Weintraub E. et al. 2014 NEJM DOI: 10.1056/NEJMoa1311738 Yih W.K. et al. 2014 NEJM DOI: 10.1056/NEJMoa1303164.

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