# 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

**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)

**First published:** 01/02/2024

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Institution

# Contact details

**Study institution contact**

Call Center EU Clinical Trials
Vx.publicdisclosureglobal@gsk.com

**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

**Medicinal product name**

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)

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**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.

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**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

## 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)**

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