

# 104435 - Post-Authorization Safety Study (PASS) of Post-Marketing Surveillance for Intussusception Following Rotarix Introduction into the Instituto Mexicano del Seguro Social (IMSS) in Mexico

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS6103

### Study ID

31671

### DARWIN EU® study

No

### Study countries

☐ Mexico

## Study description

GSK Biologicals' rotavirus vaccine, Rotarix has been recommended for universal use targeting infants through the Expanded Program on Immunization (EPI) in Mexico. This protocol describes a Phase IV safety study in Mexico designed to further evaluate the safety profile of Rotarix with regard to intussusception (IS). The data generated by this study will be useful for public health officers and policy makers in confirming the safety profile of Rotarix. This is a post marketing, Phase IV, observational, prospective, self-controlled case series, vaccine safety study including: a) active hospital-based surveillance, conducted in approximately 60 to 90 IMSS health facilities with pediatric surgery service, to identify all definite IS cases in children younger than one year of age among IMSS members, b) a self-controlled case series (SCCS) design/analysis to assess the temporal association with Rotarix of the IS ascertained through active surveillance.

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## Study status

Finalised

## Research institutions and networks

### Institutions

Medical Research Unit on Infectious Diseases,  
Paediatrics Hospital, National Medical Centre-  
Century XXI, IMSS

### Contact details

### **Study institution contact**

Call Center EU Clinical Trials

Vx.publicdisclosureglobal@gsk.com

Study contact

[Vx.publicdisclosureglobal@gsk.com](mailto:Vx.publicdisclosureglobal@gsk.com)

### **Primary lead investigator**

Call Center EU Clinical Trials

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual: 25/10/2006

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### **Study start date**

Actual: 22/01/2008

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### **Date of final study report**

Actual: 18/10/2011

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline Biologicals

## Regulatory

## Was the study required by a regulatory body?

Yes

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## 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

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#### Study type:

Non-interventional study

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#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

#### Data collection methods:

Secondary use of data

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#### Main study objective:

To assess the temporal association between Rotarix administration and definite IS occurrence within 31 days (Day 0 to Day 30) following vaccination.

## Study Design

## **Non-interventional study design**

Other

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## **Non-interventional study design, other**

Self-controlled case series

# Study drug and medical condition

## **Name of medicine**

ROTARIX

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## **Medical condition to be studied**

Intussusception

# Population studied

## **Short description of the study population**

Children younger than one year of age among Instituto Mexicano del Seguro Social (IMSS) members who has received Rotarix.

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## **Age groups**

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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## **Estimated number of subjects**

789

# Study design details

## Outcomes

Occurrence of definite IS episodes within Day 0 to Day 30 following vaccination.  
Occurrence of definite IS episodes within Day 0 to Day 15 following vaccination.  
Yearly occurrence of definite IS episodes (regardless of vaccination status).

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## Data analysis plan

SCCS methodology with adjustment by one month age interval was used to assess temporal associations between Rotarix administration and IS. Risk periods: 30 days (primary) and 16 days (secondary objectives) risk period after each dose. Control period: started at 31 days after each Rotarix dose and continued up to one year of age. Alpha was adjusted similar to the O'Brien-Fleming adjustment. For an overall alpha of 0.05, the interim analysis was performed with an alpha of 0.01 while the final analysis was performed with an alpha of 0.045. Primary objective was considered reached if upper limit (UL) of 95.5% CI (alpha = 0.045) of the relative incidence (RI) of the IS episode after each Rotarix dose is less than the RI corresponding to the consensus risk estimate of Rotashield of 1/10 000: Dose 1 RI=2.67, Dose 2 RI=1.59. Yearly (2008-2010) incidence of IS, with its exact 95% CIs was calculated for the entire population <1 year of age with membership in the IMSS system.

## Documents

### Study publications

[Velázquez FR](#), [Colindres RE](#), [Grajales C](#), [Hernández MT](#), [Mercadillo MG](#), [Torres FJ](#),...

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## 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)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown