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.

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

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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: 25/10/2006

Study start date

Actual: 22/01/2008

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

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 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

Non-interventional study design, other

Self-controlled case series

Study drug and medical condition

Medicinal product name

ROTARIX

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.

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

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).

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,...

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown