

# Post-marketing study to assess the risk of intussusception after immunization with GlaxoSmithKline (GSK) Biologicals' oral live-attenuated human rotavirus vaccine in infants less than 1 year old in Latin America (212329)

**First published:** 06/08/2025

**Last updated:** 10/03/2026

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000701

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### Study ID

1000000701







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### DARWIN EU® study

No

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### Study countries

-  Argentina
  -  Colombia
  -  Dominican Republic
  -  Honduras
  -  Mexico
  -  Panama
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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### GlaxoSmithKline (GSK)

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

**Last updated:** 01/02/2024

**Institution**

## Contact details

### Study institution contact

Call Center EU GSK Clinical Trials RD.CTT-  
globalmailbox@gsk.com

**Study contact**

[RD.CTT-globalmailbox@gsk.com](mailto:RD.CTT-globalmailbox@gsk.com)

## Primary lead investigator

Call Center EU GSK Clinical Trials

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 20/06/2025

Actual: 04/03/2025

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### Study start date

Planned: 16/12/2025

Actual: 16/12/2025

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### Date of final study report

Planned: 05/05/2028

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline Biologicals

## Study protocol

[Protocol Amendment 1.1 Anonymised 19 May 2025.pdf \(4.13 MB\)](#)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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

Not applicable

**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:**

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Study design:**

A hospital-based, observational, multicenter, prospective matched case-control study

**Main study objective:**

To evaluate post-authorization, the risk of definite IS following immunization with Rotarix PCV-free liquid vaccine in infants less than 1 year old in Latin America (LATAM).

## Study Design

**Non-interventional study design**

Case-control

## Study drug and medical condition

**Medicinal product name**

ROTARIX

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**Anatomical Therapeutic Chemical (ATC) code**

(J07BH01) rota virus, live attenuated  
rota virus, live attenuated

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**Medical condition to be studied**

Intussusception

## Population studied

**Short description of the study population**

The source population for this study will be infants (6 weeks to less than (<) 1 year of age at the time of intussusception [IS] diagnosis) visiting or hospitalized

in a recruiting hospital and who meet the study eligibility criteria at the time of entry into the study.

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### **Age groups**

- Infants and toddlers (28 days – 23 months)
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### **Estimated number of subjects**

1603

## **Study design details**

### **Setting**

The study will include participants who will be divided into Cases and Controls. Cases include all infants hospitalized or visiting the hospital emergency room (ER) for definite IS at the participating hospitals during the study period and aged between 6 weeks and 1 year of age at the time of diagnosis of IS. Cases will be identified by periodic reviews of pediatric ward admission and ER logbook(s).

For each case, 6 controls hospitalized or visiting the hospital outpatient clinic or ER with no gastro-intestinal symptoms (including gastro-enteritis and IS) in the same participating hospital, on the same day as the case ( $\pm 7$  days), will be included after matching by age ( $\pm 2$  weeks) at index date.

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### **Outcomes**

- Odds ratio of vaccine exposure to a first dose of RV vaccine between cases (IS) and controls
- Odds ratio of vaccine exposure to a second dose of RV vaccine between cases (IS) and controls
- Incidence risk ratio of definite IS comparing 3 risk windows after the first dose

of RV vaccine to a control window.

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### **Data analysis plan**

To estimate the vaccine exposure between cases and controls, a conditional logistic regression model will be used, the matched odds ratio of vaccine exposure between cases and controls, 95% CI, and p-values will be presented. To compare the incidence of IS between the risk period and the control period, a Poisson regression stratified by subject will be used and the incidence rate ratio of IS (risk/control), 95% CI, and p-values will be presented.

## 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 source(s)**

Other data source

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### **Data source(s), other**

Medical records, parent(s)/legally acceptable representative (LAR[s]) interviews, vaccination cards and immunization registries.

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## **Data sources (types)**

Other

Spontaneous reports of suspected adverse drug reactions

Vaccination registry

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## **Data sources (types), other**

Medical records

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Yes

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### **Check completeness**

Yes

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### **Check stability**

Yes

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### **Check logical consistency**

Yes

## Data characterisation

**Data characterisation conducted**

Yes