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)

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Study Planned

Administrative details

EU PAS number

EUPAS1000000701

Study ID

1000000701

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Colombia
- [ ] Dominican Republic
- [ ] Honduras
- [ ] Mexico
- [ ] Panama

Study status

Planned

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact

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

Study contact

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

Study start date

Planned: 29/01/2026

Date of final study report

Planned: 25/05/2028

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

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

Anatomical Therapeutic Chemical (ATC) code

(J07BH01) rota virus, live attenuated

rota virus, live attenuated

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.

Age groups

- Infants and toddlers (28 days – 23 months)

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 (±7 days), will be included after matching by age (±2 weeks) at index date.

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.

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

Data source(s), other

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

Data sources (types)

Other

Spontaneous reports of suspected adverse drug reactions

Vaccination registry

Data sources (types), other

Medical records

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes