# Background rates of disease in Latin American children in view of future vaccine safety assessment

**First published:** 02/02/2015

**Last updated:** 30/03/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS8502

**Study ID**

19623

**DARWIN EU® study**

No

**Study countries**

- [ ] Argentina
- [ ] Brazil
- [ ] Chile
- [ ] Colombia

- [ ] Dominican Republic
- [ ] Finland
- [ ] Honduras
- [ ] Mexico
- [ ] Nicaragua
- [ ] Panama
- [ ] Peru
- [ ] Venezuela, Bolivarian Republic of

**Study description**

Estimates of background rates of potential adverse events are an essential part of monitoring and assessing possible vaccine safety concerns (1). Accurate background rates are needed to allow distinguishing genuine safety concerns from events that are temporarily associated but not causally linked to vaccination. GlaxoSmithKline (GSK) has carried out one of the largest trials in Latin America to assess the safety and efficacy of the Rotavirus vaccine (Study 023). A total of 63,225 healthy infants from 11 Latin American countries and Finland, divided over a study arm (receiving two oral doses of the human rotavirus vaccine (Rotarix, GSK) 31,673 infants) or a control arm (receiving two doses of placebo, 31,552 infants) were followed-up to investigate the safety and efficacy of the vaccine (2). Serious adverse events were captured by an active-surveillance system in all medical facilities. Outcomes were recaptured during the scheduled visits, if missed by the active-surveillance system. This trial offers a unique opportunity to increase our knowledge on the background rates of selected medical events in this region.

**Study status**

Finalised

## Research institutions and networks

# Institutions

## P95 Clinical and Epidemiology Services

- [ ] Belgium
- [ ] Colombia
- [ ] Netherlands
- [ ] South Africa
- [ ] Thailand
- [ ] United States

**First published:** 07/11/2022

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Institution | Laboratory/Research/Testing facility | Non-Pharmaceutical company | ENCePP partner

# Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Thomas Verstraeten

Primary lead investigator

## Study timelines

**Date when funding contract was signed**
Planned: 18/03/2014

Actual: 18/03/2014

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**Study start date**
Planned: 02/02/2015

Actual: 02/02/2015

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**Date of final study report**
Planned: 01/07/2017

Actual: 01/06/2017

## Sources of funding

- Other

## More details on funding

P95

## Regulatory

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

No

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

Not applicable

# Methodological aspects

## Study type

**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:**

Other

**If ‘other’, further details on the scope of the study**

Baseline rates

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To define background rates of disease in Latin American children

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Secondary use of a randomized clinical trial i.e. GSK Rotarix study 023.

## Study drug and medical condition

**Medicinal product name**

ROTARIX

**Medical condition to be studied**

Diarrhoea

Vomiting

Dehydration

Hypovolaemic shock

Pneumonia

Seizure like phenomena

# Population studied

**Short description of the study population**

Healthy infants from 11 Latin American countries and Finland.

**Age groups**

- Infants and toddlers (28 days – 23 months)

**Estimated number of subjects**

63225

# Study design details

**Outcomes**

Incidence rates (/100.000 person years) for a list of selected medical events grouped by system organ class (MedDRA)

**Data analysis plan**

Incidence rates for selected medical events (MedDRA) will be calculated for Latin America overall, as well as country- and sex-specific incidence rates. Data from both study arms of the GSK study 023 will be combined as in ‘real-life’ vaccinated and unvaccinated subpopulations co-exist and furthermore, no significant risk differences in the selected medical events between vaccinated and unvaccinated children were detected in this study. If possible, 95% CI based on the assumption of a Poisson distribution for event counts will be calculated. If the number of cases is sufficiently large, age- and if applicable, season-specific incidence rates will be calculated as well. Because of the longitudinal follow-up of the 023 study, the presence of repeated and/or correlated events will be investigated and appropriate statistical measures taken, if needed. The results will be summarized in a Table. All statistical analyses will be conducted using SAS.

## Documents

**Study results**

Published paper Background rates 2017.pdf (793.4 KB)

**Study publications**

Ruiz-Palacios GM, Perez-Schael I, Velazquez FR, et al. Safety and efficacy of a…

# 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**

GSK Rotarix study 023

**Data sources (types)**

Other

**Data sources (types), other**

clinicalstudydatarequest.com, Secondary use of a randomized clinical trial, i.e. GSK Rotarix study 023.

## 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