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

Last updated: 21/02/2025

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

Study start date
Planned: 02/02/2015

Actual: 02/02/2015

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

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

Not applicable

Methodological aspects

Study type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

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

Baseline rates

Data collection methods:

Secondary use of data

Main study objective:

To define background rates of disease in Latin American children

Study Design

Non-interventional study design

Other

Non-interventional study design, other

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

Study drug and medical condition

Name of medicine

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