Post-marketing surveillance to monitor the incidence of intussusception after large-scale vaccination with Reassortant Rotavirus Vaccine, Live, Oral, Pentavalent (Vero Cell) (ROTATEQ®) in Chinese infants using the Ningbo Regional Health Information Platform (NRHIP)

First published: 02/07/2020

Last updated: 27/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS35812

Study ID

47560

DARWIN EU® study

No

Study countries

China

Study description

Rotavirus (RV) is the leading cause of severe diarrhea in infants and young children. In China, RV caused over 40% of diarrhea hospitalization and about 30% of diarrhea related outpatients visits in children aged < 5 years. Intussusception (IS) is a recognized and well-characterized safety concern in infants. The study objective was to assess the overall feasibility of conducting the study using the Ningbo Regional Health Information Platform (NRHIP), by assessing the IS diagnosis validity, the completeness of follow-up and the quality of linkage between the immunization register and Electronic Medical Records. The primary objective was to assess the incidence of IS (confirmed cases, Brighton Level 1) occurring within 3 months after vaccination with ROTATEQ® in Chinese infants. The secondary objectives were as follows: a) To describe the occurrence of IS (confirmed cases, Brighton Level 1) in the periods 1 to 7 days, 1 to 14 days, 1 to 21 days, 1 to 42 days and 1 day to 3 months following any dose of ROTATEQ ® in Chinese infants, b) to assess the incidence of IS (confirmed cases, Brighton Level 1) among Chinese infants in the same age range as the infants vaccinated with ROTATEQ® but did not receive any rotavirus vaccine, and c) to calculate the relative risk (RR) of IS in children vaccinated with ROTATEQ ® compared to children from the same birth cohort and within the same age range who did not receive any rotavirus vaccine.

Study status

Finalised

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

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Institution | Pharmaceutical company

Contact details

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Study timelines

Date when funding contract was signed

Actual: 11/06/2020

Study start date

Planned: 29/03/2021

Actual: 15/03/2021

Data analysis start date
Planned: 31/03/2022

Actual: 19/03/2022

Date of final study report
Planned: 20/05/2022

Actual: 20/05/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Study protocol

V260-075-00-v3-China PMC_final redaction.pdf (739.5 KB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To assess the incidence of IS (confirmed cases, Brighton Level 1) occurring within 3 months after vaccination with ROTATEQ® in Chinese infants.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Intussusception

Population studied

Short description of the study population

The study population is defined as all infants aged 6 to 45 weeks from December 2018 to June 2021 from the NRHIP immunization register, including infants vaccinated with ROTATEQ® (“vaccinated infants”) as well as infants from the same birth cohorts, who received at least one type 1 vaccine but no rotavirus vaccine (“unvaccinated infants”).

Inclusion criteria

• All infants aged 6 to 45 weeks from December 2018 to June 2021 from the NRHIP immunization register.

• Infants who received at least one dose of ROTATEQ® at age 6 to 12 weeks as recorded in the NRHIP immunization register will be considered vaccinated infants;

• Infant from the same birth cohort as the “vaccinated infants” who received at least one dose of a type 1 childhood vaccines but no rotavirus vaccine as recorded in the NRHIP immunization register will be considered unvaccinated infants.

Exclusion criteria

• Vaccinated infants:

o Infants with IS before they received the first dose of ROTATEQ®;

o Infants who were vaccinated out of the indicated age schedule, i.e., who received a first vaccine dose before 6 weeks or after 12 weeks of age and/or any dose
after 32 weeks of age;

o Infants who received one or more doses of LLR or any other RV vaccines in addition to ROTATEQ® during the study period;

o Infants without any recorded type 1 vaccination at age 8 to 9 months or until their individual end of follow-up three months after their last ROTATEQ® dose

(whatever comes first) as those infants are considered to be lost to follow-up.

• Unvaccinated infants

o Infants with IS prior to 6 weeks of age;

o Infants without any recorded type 1 vaccination at age 8 to 9 months are considered to be lost to follow-up.

Age groups

- Infants and toddlers (28 days – 23 months)

Estimated number of subjects

61.716

Study design details

Outcomes

The incidence of IS (confirmed cases, Brighton Level 1) occurring within 3 months after vaccination with ROTATEQ® in Chinese infants. 1. Occurrence of IS 1 to 7 days, 1 to 14 days, 1 to 21 days, 1 to 42 days and 1 day to 3 months following any dose of ROTATEQ ® 2. Incidence of IS in the same age range as the infants vaccinated with ROTATEQ® but did not receive any rotavirus vaccine. 3. Relative risk (RR) of IS in children vaccinated with ROTATEQ ® compared to similar children who did not receive any rotavirus vaccine.

Data analysis plan

The incidence of intussusception (IS) occurring within 3 months after vaccination with ROTATEQ® will be estimated. The occurrence of IS cases will be described with respect to the time-interval post-vaccination and in relation to dose number. We will compare the incidence rate (per 100,000 person-years) of IS in vaccinated infants to unvaccinated infants during the concurrent period (December 2018 to June 2021).

Documents

Study results

V260-075-CSR_final redaction.pdf (1.14 MB)

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

Ningbo Regional Health Information Platform (NRHIP) China

Data sources (types)

Other

Data sources (types), other

Regional health data platform

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

No