Post-marketing study to assess serotype-specific effectiveness of Reassortant Rotavirus Vaccine, Live, Oral, Pentavalent (Vero Cell) (ROTATEQ®) in China (V260-077)

First published: 03/09/2020

Last updated: 21/05/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS36666

Study ID

48721

DARWIN EU® study

No

Study countries

☐ China

Study description

In clinical trials and post-marketing studies abroad, ROTATEQ® demonstrated consistently high efficacy and effectiveness against severe rotavirus (RV) gastroenteritis (RVGE) of >90%. Serotype specific efficacy and effectiveness against genotypes G2P4, G3P8 and G4P8 was > 80% in those studies. However, in the China Phase 3 trial, serotype-specific efficacy was only demonstrated for RV serotypes G1 and G9, and not for G2, G3 and G4 because those serotypes were not circulating in the study region during the period when the study was performed.

Study status

Ongoing

Research institutions and networks

Institutions

Merck & Co.

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Merck Sharp & Dohme Rahway, New Jersey

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/11/2019

Actual: 31/03/2020

Study start date

Planned: 30/09/2020

Actual: 16/09/2020

Data analysis start date

Planned: 30/04/2025

Actual: 19/04/2025

Date of final study report

Planned: 30/04/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Study protocol

V260-077-00-v2-China PMC-Prot_Final Redaction Part 1 Pages 1-28.pdf(631.4 KB)

V260-077-V6.0-final-redaction.pdf(700.3 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 type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The objective of this non-interventional study is to assess the serotype-specific effectiveness of ROTATEQ® after large scale use in China

Study drug and medical condition

Name of medicine

ROTATEQ

Anatomical Therapeutic Chemical (ATC) code

(J07BH02) rota virus, pentavalent, live, reassorted

rota virus, pentavalent, live, reassorted

Medical condition to be studied

Gastroenteritis rotavirus

Population studied

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Estimated number of subjects

7600

Study design details

Outcomes

Rotavirus acute gastroenteritis (RVGE) positive for at least one of the serotypes G2/G3/G4 in children who received treatment in the hospital. Rotavirus acute gastroenteritis (RVGE) positive for at least one of the serotypes G1/G2/G3/G4/G9 in children who received treatment in the hospital.

Data analysis plan

A descriptive analysis of the distribution of values observed for each variable will be provided. Search for outliers, logical errors and necessary corrections will be made.

The following indicators will be computed (for each hospital and by year, if relevant): Number of acute gastroenteritis (AGE) cases in children age-eligible to be vaccinated with ROTATEQ®, Number of rotavirus acute gastroenteritis (RVGE) cases in children age-eligible to be vaccinated with ROTATEQ®, and Number of G1, G2, G3, G4, G9 RVGE cases in children age-eligible to be vaccinated with ROTATEQ®.

Vaccine effectiveness (VE) will be estimated once the sample size is sufficient to reach 80% statistical power. VE will be computed as: 1- odds ratio (OR), where OR is the ratio of the likelihood of ROTATEQ® vaccination among RVGE to the likelihood of vaccination among RV negative AGE.

Documents

Study, other information

V260-077-00-v2-China PMC-Prot_Final Redaction Part 2 Pages 29-51_1.pdf (349.89 KB)

V260-077-00-v4_protocol_final-redaction.pdf(1.56 MB)

V260-077-00-v5-Protocol_final-redaction.pdf(395.08 KB)

Data management

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