Effectiveness of ROTATEQ® when administered with intervals greater than 10 weeks between doses in Chinese children: an observational study of V260-077 study participants with longer dosing interval (V260-080)

First published: 17/09/2025

Last updated: 13/10/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000730

Study ID

1000000730

DARWIN EU® study

No

Study countries

China

Study description

The main objective of the study is to assess the vaccine effectiveness of ROTATEQ® against all types of rotavirus acute gastroenteritis (RVGE) when administered in Chinese children with at least one dosing interval of greater than 10 weeks between doses 1 and 2 and/or 2 and 3.

Study status

Ongoing

Research institutions and networks

Institutions

Merck Sharpe & Dohme LLC, Hangzhou Tigermed Consulting Co.,Ltd

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC
ClinicalTrialsDisclosure@msd.com

Study contact

ClinicalTrialsDisclosure@msd.com

Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 16/11/2023

Actual: 16/11/2023

Study start date
Planned: 31/08/2025

Actual: 22/09/2025

Data analysis start date
Planned: 30/09/2025

Actual: 30/09/2025

Date of final study report
Planned: 31/01/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

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 type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is a secondary data collection study with Test-Negative Case-Control design. It will use structured data from the post-licensure study, V260-077. No additional data are being collected in this study.

Main study objective:

The main objective of this study is to assess the vaccine effectiveness of ROTATEQ® against all types of RVGE when the vaccine is administered in children with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Medicinal product name

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

Short description of the study population

The study population includes children from the enrollment population of the V260-077 study, with documented Rotavirus (RV) test results and who received the ROTATEQ vaccine with at least one dosing interval greater than 10 weeks. The estimated number of participants will include the number of children who were vaccinated with intervals > 10 weeks plus the non-vaccinated children.

Age groups

- **Paediatric Population (< 18 years)**
  - Neonate
    - Preterm newborn infants (0 – 27 days)
    - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)

Estimated number of subjects

3800

Study design details

Setting

The study population includes children from the enrollment population of the V260-077 study, with documented Rotavirus (RV) test results and who received the ROTATEQ vaccine with at least one dosing interval greater than 10 weeks and excludes children with incomplete ROTATEQ® schedule and children who had received ROTATEQ® within 14 days before the onset of AGE.

Outcomes

The study outcome is the eligible RV positive/negative Acute gastroenteritis (AGE) in children receiving treatment in hospitals from the V260-077 study. In V260-077 study, AGE is defined as 3 or more watery or looser than normal

stools within 24 hour period and/or forceful vomiting.
For the primary objective, all RVGE cases who did not meet the exclusion criteria, identified from the V260-077 study will be defined as “cases”.
Children are considered a “control” for all objectives if they have RV negative AGE, receiving treatments in hospitals from V260-077 enrollment dataset.

Data analysis plan

Vaccine effectiveness (VE) will be calculated by comparing the odds ratio of “vaccination with intervals >10 weeks versus unvaccinated” among cases (RV positives) compared to controls (RV negatives), using multivariate logistic regression adjusted for potential confounders.
The VE will be calculated as (1-odds ratio)×100%.

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

Study V260-077 database

Data sources (types)

Non-interventional study

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

Yes