

# 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:** 30/06/2026

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000730

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### Study ID

1000000730

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### DARWIN EU® study

No

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### Study countries

### **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.

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### **Study status**

Finalised

## 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](mailto:ClinicalTrialsDisclosure@msd.com)

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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: 16/11/2023

Actual: 16/11/2023

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### **Study start date**

Planned: 31/08/2025

Actual: 22/09/2025

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### **Data analysis start date**

Planned: 30/09/2025

Actual: 25/09/2025

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### **Date of final study report**

Planned: 19/06/2026

Actual: 18/06/2026

## 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

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

Not applicable

**Methodological aspects**

**Study type**

**Study type list**

**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:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**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

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**Anatomical Therapeutic Chemical (ATC) code**

(J07BH02) rota virus, pentavalent, live, reassorted  
rota virus, pentavalent, live, reassorted

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**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.

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## **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)
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## **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.

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## **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.

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### **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  $(1 - \text{odds ratio}) \times 100\%$ .

## 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

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### **Data sources (types)**

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

Yes