Observational study to assess effectiveness of ROTATEQ® against acute gastroenteritis (AGE) due to rotavirus (regardless of type) and by type in China

First published: 23/09/2025

Last updated: 14/04/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000734

Study ID

1000000734

DARWIN EU® study

No

Study countries

☐ China

Study description

This study aims to leverage the dataset of the ROTATEQ® vaccine effectiveness (VE) post-licensure study in China (Protocol V260-077) to assess the VE of ROTATEQ® against rotavirus acute gastroenteritis (RVGE) (regardless of type), as well as type-specific VE against individual RV type (including non-vaccine types).
The main objective of this study is to assess the effectiveness of ROTATEQ® against all types of RVGE in children treated in the hospital for acute gastroenteritis (AGE).

Study status

Ongoing

Research institutions and networks

Institutions

Merck Sharpe & Dohme LLC

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
Actual: 16/11/2023

Study start date
Actual: 22/09/2025

Data analysis start date
Actual: 25/09/2025

Date of final study report
Planned: 15/05/2026

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:

Disease /health condition

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. All RVGE cases (ELISA positive for RV test) identified from the V260-077 study will

be defined as “cases”. No additional data are being collected.

Main study objective:

To assess the effectiveness of ROTATEQ® against all types of RVGE in children treated in the hospital for AGE.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Medicinal product name

ROTATEQ

Study drug International non-proprietary name (INN) or common name

ROTAVIRUS SEROTYPE G1 HUMAN-BOVINE ROTAVIRUS REASSORTANTS (LIVE) PRODUCED ON VERO CELLS

ROTAVIRUS SEROTYPE G2 HUMAN-BOVINE ROTAVIRUS REASSORTANTS (LIVE) PRODUCED ON VERO CELLS

ROTAVIRUS SEROTYPE G3 HUMAN-BOVINE ROTAVIRUS REASSORTANTS (LIVE) PRODUCED ON VERO CELLS

ROTAVIRUS SEROTYPE G4 HUMAN-BOVINE ROTAVIRUS REASSORTANTS (LIVE) PRODUCED ON VERO CELLS

ROTAVIRUS SEROTYPE P1[8] HUMAN-BOVINE ROTAVIRUS REASSORTANTS (LIVE) PRODUCED ON VERO CELLS

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

Study population from the V260-077 study: Children (infants not older than 12 weeks when ROTATEQ® was introduced in the catchment areas of the selected hospitals) with documented RV test results, age-eligible to be fully vaccinated with 3 doses of ROTATEQ®, and receiving treatment for AGE in hospitals.

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)
  - Children (2 to < 12 years)

Special population of interest

Other

Special population of interest, other

Children with rotavirus gastroenteritis (regardless of type)

Estimated number of subjects

7600

Study design details

Setting

Study population from the V260-077 study: Children (infants not older than 12 weeks when ROTATEQ® was introduced in the catchment areas of the selected hospitals) with documented RV test results, age-eligible to be fully vaccinated with 3 doses of ROTATEQ®, and receiving treatment for AGE in hospitals. "Age-eligible" means children who have minimum age of 16 weeks at the time of AGE onset and maximum age of 12 weeks (upper age limit for dose 1) when ROTATEQ® was launched in the respective hospital catchment area.

Comparators

All RV negative AGE cases (ELISA negative for RV test) identified from V260-077 study will be defined as “controls”.

Outcomes

RV positive AGE (serotype-specific) receiving treatments in hospitals.

Data analysis plan

For the primary objective, all RVGE cases (ELISA positive for RV test) identified from the V260-077 study will be defined as “cases”. All RV negative AGE cases (ELISA negative for RV test) identified from V260-077 study will be defined as “controls”.

The study exposure of interest is ROTATEQ ® vaccination status. Odds ratios for ROTATEQ ® vaccination for case compared with test-negative controls will be estimated by a multivariate logistic regression, adjusting for potential confounders.

The VE will be calculated as (1-odds ratio)×100%.

Data management

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 sources (types)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction