A Study of the Effectiveness and Safety of a New Formulation of RotaTeq™ in Routine Use in a Developing World Setting

First published: 26/01/2015

Last updated: 27/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8342

Study ID

47461

DARWIN EU® study

No

Study countries

Mali

Study description

This non-interventional study is to monitor the effectiveness and safety of a new enhanced thermostable Vaccine Vial Monitor-Compatible (VVMC) formulation of Rotavirus Vaccine, Live, Oral (RotaTeq) in children aged <5 years in routine conditions of use in public health practice in Mali, Africa. The study will descriptively compare rates of rotavirus moderate-to-severe diarrhea (MSD) and bowel intussusception among children vaccinated with the current formulation of RotaTeq to that of children vaccinated with the new VVMC formulation of RotaTeq (once it is available).

Study status

Finalised

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

First published: 01/02/2024

Last updated: 08/07/2025

Institution | Pharmaceutical company

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC
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Study contact

ClinicalTrialsDisclosure@merck.com

Primary lead investigator

Karen Kotloff

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 20/10/2014

Study start date

Planned: 11/05/2015

Actual: 06/05/2015

Data analysis start date

Planned: 31/01/2018

Actual: 31/01/2018

Date of final study report

Planned: 04/09/2018

Actual: 14/09/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharpe & Dohme LLC

Study protocol

V260-073-00 Abstract.pdf (820.66 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To compare rates of rotavirus MSD and rates of confirmed intussusception among children vaccinated with three doses of the current formulation of RotaTeq to that of children vaccinated with three doses of the new formulation.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, pre-post surveillance study

Study drug and medical condition

Medical condition to be studied

Rotavirus infection

Population studied

Short description of the study population

Approximately 32,000 children under five years of age reside in the demographic surveillance system (DSS) catchment areas of Bamako.

To be eligible for inclusion in the Moderate-to-Severe Diarrhea (MSD) surveillance study, subjects must meet the following inclusion criteria:

1) Less than five years of age at the time of the study visit

2) Parent(s)/Guardians(s) provide written informed consent for her/her child to participate in the study

3) Belongs to the DSS

4) Seeking care at a Sentinel Health Center (SHC) for diarrhea (three or more loose stools with the previous 24 hours) that has the following characteristics:

• New (onset after seven or more days diarrhea-free)

• Acute (onset in the previous seven days), and

• Meets at least one of the following criteria for MSD:

i. Sunken eyes (confirmed for the parent/caretaker as more than normal)

ii. Loss of skin turgor (abdominal skin pinch with slow (but less than two seconds) or very slow (greater than two seconds) recoil).

iii. Intravenous rehydration recommended; or

iv. Hospitalization recommended

Additionally, subjects enrolled in the MSD study may not meet the following exclusion criteria:

1) Subject diagnosed with dysentery

2) Any condition that, in the opinion of the investigator, might interfere with the evaluation of study objectives.

3) Enrollment in the study in the past 60 days

Age groups

- Children (2 to < 12 years)

- Infants and toddlers (28 days – 23 months)

Estimated number of subjects

5.000

Study design details

Outcomes

1. The rate of diarrhea that is rotavirus-positive occurring 14 or more days after vaccination with the third dose of RotaTeq versus VVMC RotaTeq2. The incidence of intussusception among vaccinated infants with RotaTeq versus VVMC RotaTeq

Data analysis plan

This study will estimate rates of rotavirus MSD and intussusception pre and post the introduction of the VVMC formulation. These analyses are descriptive and do not formally test hypotheses. Descriptive data analysis of the aggregated information will be performed and the results displayed in tabulated form. Descriptive statistics will be used to describe patient demographics and vaccine coverage and displayed in summary tables.

Documents

Study results

V260 P073 CSR_final-redaction.pdf (955.33 KB)

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 sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection

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