V260 Study: Concomitant Use of V260 and INFANRIX™ Hexa in Healthy Infants (V260-010)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00258154

First received: November 15, 2005
Last updated: October 5, 2015
Last verified: October 2015
History of Changes

Purpose

The study is being conducted to demonstrate that the vaccine to prevent gastroenteritis due to rotavirus may be administered concomitantly with INFANRIX(tm)hexa without impairing the safety and immunogenicity of either vaccine.

Condition	Intervention	Phase
Rotavirus Disease	Biological: Rotavirus Vaccine, Live, Oral, Pentavalent Biological: Comparator: placebo Biological: Comparator: Infanrix(tm) Hexa	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: Safety and Immunogenicity of Concomitant Use of V260 and INFANRIX™ Hexa in Healthy Infants

Resource links provided by NLM:

MedlinePlus related topics: Tetanus, Diphtheria, and Pertussis Vaccines

Drug Information available for: Boostrix Rotavirus vaccine, live, oral, pentavalent Adacel

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Immunogenicity of INFANRIX™ Hexa in Relation to Anti-hepatitis B Surface Antigen HBsAg, Predose 1 [Time Frame: Day 1 of a 3-dose

regimen] [Designated as safety issue: No]

Geometric Mean Titer (GMT)/antibody responses to RotaTeq™ and INFANRIX™ in relation to anti-hepatitis B surface antigen HBsAg at start of a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Anti-hepatitis B Surface Antigen HBsAg , at 42 Days After a 3-dose Regimen [Time Frame: 42 days after 3-dose regimen] [Designated as safety issue: No]

  GMT/antibody responses to RotaTeq™ and INFANRIX™ in relation to anti-hepatitis B surface antigen HBsAg at 42 days after 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Anti-polyribosylribitol Phosphate PRP, Predose 1 [Time Frame: Day 1 of 3-dose regimen] [Designated as safety issue: No]

  GMT/antibody responses to RotaTeq™ and INFANRIX™ hexa in relation to serum anti-polyribosylribitol phosphate PRP at start of 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Anti-polyribosylribitol Phosphate PRP at 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen] [Designated as safety issue: No]

  GMT/antibody responses to RotaTeq™ and INFANRIX™ hexa in relation to serum anti-polyribosylribitol phosphate PRP at 42 days after a 3-dose regimen

Secondary Outcome Measures:

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 1 When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)] [Designated as safety issue: Yes]

  GMT of Poliovirus Type 1 in subjects with even allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 1 When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen] [Designated as safety issue: Yes]

  GMT of Poliovirus Type 1 in subjects with even allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa , 42 days after a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 2 When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Pre-dose (Day 1 of a 3-dose regimen)] [Designated as safety issue: Yes]

  GMT of Poliovirus Type 2 in subjects with even allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 2 When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after in a 3-dose regimen] [Designated as safety issue: Yes]

  GMT of Poliovirus Type 2 in subjects with even allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 3 When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)] [Designated as safety issue: No]

  GMT of Poliovirus Type 3 in subjects with even allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 3 When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen] [Designated as safety issue: No]

  GMT of Poliovirus Type 3 in subjects with even allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Diphtheria Toxoid When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)] [Designated as safety issue: No]

  GMT of diphtheria toxoid in subjects with odd allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Diphtheria Toxoid When Administered Concomitantly With

RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen] [Designated as safety issue: No]

GMT of diphtheria toxoid in subjects with odd allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Tetanus Toxoid When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)] [Designated as safety issue: No]

  GMT of tetanus toxoid in subjects with odd allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Tetanus Toxoid When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen] [Designated as safety issue: No]

  GMT of tetanus toxoid in subjects with odd allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis FHA When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)] [Designated as safety issue: No]

  GMT of pertussis FHA in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis FHA When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen] [Designated as safety issue: No]

  GMT of pertussis FHA in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Pertactin When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)] [Designated as safety issue: No]

  GMT of pertussis Pertactin in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Pertactin When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen] [Designated as safety issue: No]

  GMT of pertussis Pertactin in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Toxoid When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)] [Designated as safety issue: No]

  GMT of pertussis toxoid in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen

- Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Toxoid When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen] [Designated as safety issue: No]

  GMT of pertussis toxoid in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen

- Serum Neutralizing Antibody (SNA) Response to Serotype G1 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)] [Designated as safety issue: No]

  GMT of serotype G1 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen

- Serum Neutralizing Antibody (SNA) Response to Serotype G1 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen] [Designated as safety issue: No]

  GMT of serotype G1 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen

- Serum Neutralizing Antibody (SNA) Response to Serotype G2 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)] [Designated as safety issue: No]

GMT of serotype G2 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen

- Serum Neutralizing Antibody (SNA) Response to Serotype G2 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen] [Designated as safety issue: No]

  GMT of serotype G2 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen

- Serum Neutralizing Antibody (SNA) Response to Serotype G3 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)] [Designated as safety issue: No]

  GMT of serotype G3 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa Predose 1

- Serum Neutralizing Antibody (SNA) Response to Serotype G3 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen] [Designated as safety issue: No]

  GMT of serotype G3 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen

- Serum Neutralizing Antibody (SNA) Response to Serotype G4 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)] [Designated as safety issue: No]

  GMT of serotype G4 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa Predose 1

- Serum Neutralizing Antibody (SNA) Response to Serotype G4 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen] [Designated as safety issue: No]

  GMT of serotype G4 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen

- Serum Neutralizing Antibody (SNA) Response to Serotype P1A in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)] [Designated as safety issue: No]

  GMT of serotype P1A in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa Predose 1

- Serum Neutralizing Antibody (SNA) Response to Serotype P1A in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen] [Designated as safety issue: No]

  GMT of serotype P1A in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen

- Serum Neutralizing Antibody (SNA) Response to Serum Anti-rotavirus IgA in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)] [Designated as safety issue: No]

  GMT of serum anti-rotavirus IgA in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa Predose 1

- Serum Neutralizing Antibody (SNA) Response to Serum Anti-rotavirus IgA in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen] [Designated as safety issue: No]

  GMT of serum anti-rotavirus IgA in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen

Enrollment:	403
Study Start Date:	February 2006
Study Completion Date:	November 2006
Primary Completion Date:	November 2006 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 RotaTeq/Infanrix Hexa	Biological: Rotavirus Vaccine, Live, Oral, Pentavalent 3 doses of rotavirus vaccine live, oral, pentavalent on Day 1, 28 to 42 days post dose 1 and 28 to 42 days post dose 2 Biological: Comparator: Infanrix(tm) Hexa

	3 doses of oral Infanrix(tm) Hexa on Day 1, 28 to 42 days post dose 1 and 28 to 42 days post dose 2
Placebo Comparator: 2 Placebo/Infanrix Hexa	Biological: Comparator: placebo 3 doses of placebo to rotavirus vaccine live, oral, pentavalent on Day 1, 28 to 42 days post dose 1 and 28 to 42 days post dose 2 Biological: Comparator: Infanrix(tm) Hexa 3 doses of oral Infanrix(tm) Hexa on Day 1, 28 to 42 days post dose 1 and 28 to 42 days post dose 2

Eligibility

Ages Eligible for Study: 6 Weeks to 12 Weeks
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Healthy infant per investigator, 6 through 12 weeks of age

Exclusion Criteria:

- History of congenital abdominal disorders, intussusception, or abdominal surgery
- Known or suspected impairment of immunological function
- Known hypersensitivity to any component of the rotavirus vaccine
- Prior administration of any rotavirus vaccine
- Known hypersensitivity or contraindication to any component of INFANRIX(tm) hexa
- Any infant born from a known HBsAg-positive mother
- Prior administration of any oral polio vaccine
- Receipt of one or more doses of inactivated poliovirus vaccine, diptheria, tetanus and acellular pertussis vaccine, diptheria, tetanus and pertussis vaccine, Haemophilus influenzae type b vaccine, or any hepatitis B vaccine prior to the first vaccination, or receipt of any vaccines with these antigens at any time during the course of the study
- Fever, with a rectal temperature greater than or equal to 38.1 degree C (greater than or equal to 100.5 degree F) at the time of immunization
- History of known prior rotavirus gastroenteritis, chronic diarrhea, or failure to thrive
- Clinical evidence of active gastrointestinal illness
- Receipt of intramuscular, oral, or intravenous corticosteroid treatment within the 2 weeks prior to vaccination
- Infants residing in a household with an immunocompromised person
- Prior receipt of a blood transfusion or blood products
- Participation in another clinical study within 42 days before the beginning or anytime during the duration of the current clinical study
- Any infant who cannot be adequately followed for safety by a contact visit
- History of seizure disorders or prior history followed for safety by a contact visit
- Any condition that, in the opinion of the investigator, may interfere with the evaluation of the study objectives

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00258154

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Additional Information:

MedWatch - FDA maintained medical product safety Information EXIT

Merck: Patient & Caregiver U.S. Product Web Site EXIT

Publications:

Ciarlet M, He S, Lai S, Petrecz M, Yuan G, Liu GF, Mikviman E, Heaton PM, Panzer F, Rose T, Koller DY, Van Damme P, Schödel F. Concomitant use of the 3-dose oral pentavalent rotavirus vaccine with a 3-dose primary vaccination course of a diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated polio-Haemophilus influenzae type b vaccine: immunogenicity and reactogenicity. Pediatr Infect Dis J. 2009 Mar;28(3):177-81. doi: 10.1097/INF.0b013e31818c0161.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00258154 History of Changes
Other Study ID Numbers:	V260-010 2005_046
Study First Received:	November 15, 2005
Results First Received:	August 10, 2009
Last Updated:	October 5, 2015
Health Authority:	Belgium: Federal Agency for Medicines and Health Products, FAMHP

Additional relevant MeSH terms:
Rotavirus Infections
RNA Virus Infections
Reoviridae Infections
Virus Diseases

ClinicalTrials.gov processed this record on April 20, 2016

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This study has been completed.

Sponsor:
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ClinicalTrials.gov Identifier:
NCT00258154

First received: November 15, 2005
Last updated: October 5, 2015
Last verified: October 2015
History of Changes

Results First Received: August 10, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Rotavirus Disease
Interventions:	Biological: Rotavirus Vaccine, Live, Oral, Pentavalent Biological: Comparator: placebo Biological: Comparator: Infanrix(tm) Hexa

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

Enrollment occurred at 26 sites in Austria, Belgium, and Germany from 22Feb2006 (first subject in) to 13Nov2006 (last subject out). Cutoff date for all clinical and laboratory data from the Case Report Forms in-house was 08Jun2007. Access to the clinical database was granted on 15Jun2007.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

Excluded from randomization were patients with history of congenital abdominal disorders, intussusception, or abdominal surgery; history of known prior rotavirus disease, chronic diarrhea, or failure to thrive, clinical evidence of active gastrointestinal illness and those with fever, a

rectal temperature >38.1°C (>100.5°F) at time of immunization.

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Participant Flow: Overall Study

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa
STARTED	**201** [1]	**202** [2]
Vaccinated at Visit 1	**201**	**202**
Vaccinated at Visit 2	**198**	**198**
Vaccinated at Visit 3	**195**	**197**
COMPLETED	**192** [3]	**195** [3]
NOT COMPLETED	**9**	**7**
Adverse Event	**1**	**0**
Lost to Follow-up	**0**	**1**
Protocol Violation	**2**	**1**
Withdrawal by Subject	**3**	**4**
Patient Moved	**3**	**1**

[1] Healthy infants who started in the RotaTeq™ concomitantly with INFANRIX™ hexa group.
[2] Healthy infants who started in the Placebo concomitantly with INFANRIX™ hexa group.
[3] Subjects who completed the study.

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.
Total	Total of all reporting groups

Baseline Measures

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa	Total

Number of Participants [units: participants]	**201**	**202**	**403**
Age, Customized [units: participants]			
5 Weeks of Age and Under	**1**	**0**	**1**
6-12 Weeks of Age	**199**	**202**	**401**
Over 12 Weeks of Age	**1**	**0**	**1**
Gender [units: participants]			
Female	**104**	**102**	**206**
Male	**97**	**100**	**197**
Race/Ethnicity, Customized [units: Participants]			
Asian	**4**	**2**	**6**
Black	**10**	**11**	**21**
Multi-Racial	**1**	**2**	**3**
White	**186**	**187**	**373**

Outcome Measures

Hide All Outcome Measures

1. Primary: Immunogenicity of INFANRIX™ Hexa in Relation to Anti-hepatitis B Surface Antigen HBsAg, Predose 1 [Time Frame: Day 1 of a 3-dose regimen]

Measure Type	Primary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Anti-hepatitis B Surface Antigen HBsAg, Predose 1
Measure Description	Geometric Mean Titer (GMT)/antibody responses to RotaTeq™ and INFANRIX™ in relation to anti-hepatitis B surface antigen HBsAg at start of a 3-dose regimen
Time Frame	Day 1 of a 3-dose regimen
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All per-protocol subjects were included in the analysis of primary endpoints for polyribosylribitol phosphate (PRP) and hepatitis B surface antigen (HBsAg). Subjects listed in the Protocol Violation Memo were excluded from the immunogenicity analysis; N analyzed = number of subjects contributing to per protocol analysis.

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.

Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa
Number of Participants Analyzed [units: participants]	**185**	**184**
Immunogenicity of INFANRIX™ Hexa in Relation to Anti-hepatitis B Surface Antigen HBsAg, Predose 1 [units: mIU/mL] Geometric Mean (95% Confidence Interval)	**12.7 (10.0 to 16.1)**	**13.5 (10.5 to 17.4)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Anti-hepatitis B Surface Antigen HBsAg, Predose 1

2. Primary: Immunogenicity of INFANRIX™ Hexa in Relation to Anti-hepatitis B Surface Antigen HBsAg , at 42 Days After a 3-dose Regimen [Time Frame: 42 days after 3-dose regimen]

Measure Type	Primary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Anti-hepatitis B Surface Antigen HBsAg , at 42 Days After a 3-dose Regimen
Measure Description	GMT/antibody responses to RotaTeq™ and INFANRIX™ in relation to anti-hepatitis B surface antigen HBsAg at 42 days after 3-dose regimen
Time Frame	42 days after 3-dose regimen
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All per-protocol subjects were included in the analysis of primary endpoints for polyribosylribitol phosphate (PRP) and hepatitis B surface antigen (HBsAg). Subjects listed in the Protocol Violation Memo were excluded from the immunogenicity analysis; N analyzed = number of subjects contributing to per protocol analysis.

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa
Number of Participants Analyzed [units: participants]	**184**	**184**
Immunogenicity of INFANRIX™ Hexa in Relation to Anti-hepatitis B Surface Antigen HBsAg , at 42 Days After a 3-dose Regimen [units: mIU/mL] Geometric Mean (95% Confidence Interval)	**227.8 (189.2 to 274.2)**	**261.0 (219.3 to 310.7)**

Statistical Analysis 1 for Immunogenicity of INFANRIX™ Hexa in Relation to Anti-hepatitis B Surface Antigen HBsAg , at 42 Days After a 3-dose Regimen

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	Miettinen and Nurminen's
P Value [4]	<0.001
Percentage point difference [5]	0.0
95% Confidence Interval	-3.7 to 3.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	non-inferiority criterion is that the lower limit of the 2-sided 95% confidence interval of the proportion difference (Rotateq+INFANRIX hexa group minus Placebo+INFANRIX hexa group) for subjects who achieve serum antibody levels of ≥ 10 mIU/mL greater than -10%
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	Comparing percentage difference with the non-inferiority margin of 10 percentage point with Miettinen and Nurminen's method
[4]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[5]	Other relevant estimation information:
	Percentage point difference (RotaTeq – Placebo)

3. Primary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Anti-polyribosylribitol Phosphate PRP, Predose 1 [Time Frame: Day 1 of 3-dose regimen]

Measure Type	Primary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Anti-polyribosylribitol Phosphate PRP, Predose 1
Measure Description	GMT/antibody responses to RotaTeq™ and INFANRIX™ hexa in relation to serum anti-polyribosylribitol phosphate PRP at start of 3-dose regimen
Time Frame	Day 1 of 3-dose regimen
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All per-protocol subjects were included in the analysis of primary endpoints for polyribosylribitol phosphate (PRP) and hepatitis B surface antigen (HBsAg). Subjects listed in the Protocol Violation Memo were excluded from the immunogenicity analysis; N analyzed = number of subjects contributing to per protocol analysis.

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa
Number of Participants Analyzed [units: participants]	**184**	**184**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Anti-polyribosylribitol Phosphate PRP, Predose 1 [units: ng/mL] Geometric Mean (95% Confidence Interval)	**204.3 (181.6 to 229.8)**	**189.7 (170.0 to 211.8)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Anti-polyribosylribitol Phosphate PRP, Predose 1

4. Primary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Anti-polyribosylribitol Phosphate PRP at 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen]

Measure Type	Primary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Anti-polyribosylribitol Phosphate PRP at 42 Days After a 3-dose Regimen
Measure Description	GMT/antibody responses to RotaTeq™ and INFANRIX™ hexa in relation to serum anti-polyribosylribitol phosphate PRP at 42 days after a 3-dose regimen
Time Frame	42 days after a 3-dose regimen
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All per-protocol subjects were included in the analysis of primary endpoints for polyribosylribitol phosphate (PRP) and hepatitis B surface antigen (HBsAg). Subjects listed in the Protocol Violation Memo were excluded from the immunogenicity analysis; N analyzed = number of subjects contributing to per protocol analysis.

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa
Number of Participants Analyzed [units: participants]	**185**	**184**

Immunogenicity of INFANRIX™ Hexa in Relation to Serum Anti-polyribosylribitol Phosphate PRP at 42 Days After a 3-dose Regimen [units: ng/mL] Geometric Mean (95% Confidence Interval)	**1316 (1081 to 1603)**	**1400 (1172 to 1672)**

Statistical Analysis 1 for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Anti-polyribosylribitol Phosphate PRP at 42 Days After a 3-dose Regimen

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	Miettinen and Nurminen's
P Value [4]	0.015
Percentage point difference [5]	-3.7
95% Confidence Interval	-9.3 to 1.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	non-inferiority criterion is that the lower limit of the 2-sided 95% confidence interval of the proportion difference (Rotateq+INFANRIX hexa group minus Placebo+INFANRIX hexa group) for subjects who achieve serum antibody levels of ≥ 0.15 µg/mL greater than -10%.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	Comparing percentage difference with the non-inferiority margin of 10 percentage point with Miettinen and Nurminen's method
[4]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[5]	Other relevant estimation information:
	Percentage point difference (RotaTeq – Placebo)

5. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 1 When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)]

Measure Type	Secondary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 1 When Administered Concomitantly With RotaTeq™, Predose 1
Measure Description	GMT of Poliovirus Type 1 in subjects with even allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen
Time Frame	Predose (Day 1 of a 3-dose regimen)
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Per Protocol Analysis on Subset A (subjects with even allocation numbers)

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa
Number of Participants Analyzed [units: participants]	**97**	**67**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 1 When Administered Concomitantly With RotaTeq™, Predose 1 [units: Dilution Unit] Geometric Mean (95% Confidence Interval)	**15.1 (11.3 to 20.2)**	**18.3 (12.9 to 26.0)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 1 When Administered Concomitantly With RotaTeq™, Predose 1

6. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 1 When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen]

Measure Type	Secondary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 1 When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen
Measure Description	GMT of Poliovirus Type 1 in subjects with even allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa , 42 days after a 3-dose regimen
Time Frame	42 days after a 3-dose regimen
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis on Subset A (subjects with even allocation numbers)

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX

		Hexa
Number of Participants Analyzed [units: participants]	**95**	**68**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 1 When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [units: Dilution Unit] Geometric Mean (95% Confidence Interval)	**94.9 (68.9 to 130.6)**	**160.2 (113.6 to 225.8)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 1 When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen

7. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 2 When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Pre-dose (Day 1 of a 3-dose regimen)]

Measure Type	Secondary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 2 When Administered Concomitantly With RotaTeq™, Predose 1
Measure Description	GMT of Poliovirus Type 2 in subjects with even allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen
Time Frame	Pre-dose (Day 1 of a 3-dose regimen)
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis on Subset A (subjects with even allocation numbers)

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**97**	**67**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 2 When Administered Concomitantly With RotaTeq™, Predose 1 [units: Dilution Unit] Geometric Mean (95% Confidence Interval)	**12.8 (9.8 to 16.8)**	**12.7 (9.2 to 17.6)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 2 When Administered Concomitantly With RotaTeq™, Predose 1

8. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 2 When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after in a 3-dose regimen]

Measure Type	Secondary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 2 When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen
Measure Description	GMT of Poliovirus Type 2 in subjects with even allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen
Time Frame	42 days after in a 3-dose regimen
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis on Subset A (subjects with even allocation numbers)

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**95**	**68**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 2 When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [units: Dilution Unit] Geometric Mean (95% Confidence Interval)	**63.1 (45.8 to 86.8)**	**69.4 (48.6 to 99.2)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 2 When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen

9. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 3 When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)]

Measure Type	Secondary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 3 When Administered Concomitantly With RotaTeq™, Predose 1
Measure Description	GMT of Poliovirus Type 3 in subjects with even allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen
Time Frame	Predose (Day 1 of a 3-dose regimen)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis on Subset A (subjects with even allocation numbers)

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**97**	**67**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 3 When Administered Concomitantly With RotaTeq™, Predose 1 [units: Dilution Unit] Geometric Mean (95% Confidence Interval)	**9.0 (6.8 to 12.1)**	**7.8 (5.7 to 10.7)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 3 When Administered Concomitantly With RotaTeq™, Predose 1

10. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 3 When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen]

Measure Type	Secondary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 3 When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen
Measure Description	GMT of Poliovirus Type 3 in subjects with even allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen
Time Frame	42 days after a 3-dose regimen
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis on Subset A (subjects with even allocation numbers)

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa
Number of Participants Analyzed [units: participants]	**95**	**68**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 3 When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [units: Dilution Unit] Geometric Mean (95% Confidence Interval)	**222.9 (153.9 to 322.8)**	**263.9 (173.5 to 401.5)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Poliovirus Type 3 When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen

11. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Diphtheria Toxoid When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)]

Measure Type	Secondary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Diphtheria Toxoid When Administered Concomitantly With RotaTeq™, Predose 1
Measure Description	GMT of diphtheria toxoid in subjects with odd allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen
Time Frame	Predose (Day 1 of a 3-dose regimen)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis on Subset B (subjects with odd allocation number)

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa
Number of Participants Analyzed [units: participants]	**78**	**104**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Diphtheria Toxoid When Administered Concomitantly With RotaTeq™, Predose 1 [units: IU/mL] Geometric Mean (95% Confidence Interval)	**0.0 (0.0 to 0.0)**	**0.0 (0.0 to 0.1)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Diphtheria Toxoid When

Administered Concomitantly With RotaTeq™, Predose 1

12. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Diphtheria Toxoid When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen]

Measure Type	Secondary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Diphtheria Toxoid When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen
Measure Description	GMT of diphtheria toxoid in subjects with odd allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen
Time Frame	42 days after a 3-dose regimen
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis on Subset B (subjects with odd allocation number)

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**73**	**100**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Diphtheria Toxoid When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [units: IU/mL] Geometric Mean (95% Confidence Interval)	**0.1 (0.1 to 0.1)**	**0.1 (0.1 to 0.1)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Diphtheria Toxoid When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen

13. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Tetanus Toxoid When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)]

Measure Type	Secondary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Tetanus Toxoid When Administered Concomitantly With RotaTeq™, Predose 1
Measure Description	GMT of tetanus toxoid in subjects with odd allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen

Time Frame	Predose (Day 1 of a 3-dose regimen)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis on Subset B (subjects with odd allocation numbers)

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**76**	**104**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Tetanus Toxoid When Administered Concomitantly With RotaTeq™, Predose 1 [units: IU/mL] Geometric Mean (95% Confidence Interval)	**0.2 (0.2 to 0.4)**	**0.3 (0.2 to 0.5)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Tetanus Toxoid When Administered Concomitantly With RotaTeq™, Predose 1

14. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Tetanus Toxoid When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen]

Measure Type	Secondary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Tetanus Toxoid When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen
Measure Description	GMT of tetanus toxoid in subjects with odd allocation numbers, receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen
Time Frame	42 days after a 3-dose regimen
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis on Subset B (subjects with odd allocation numbers

Reporting Groups

	Description

RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**72**	**101**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Tetanus Toxoid When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [units: Dilution Unit] Geometric Mean (95% Confidence Interval)	**1.4 (1.1 to 1.7)**	**1.5 (1.2 to 1.8)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Tetanus Toxoid When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen

15. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis FHA When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)]

Measure Type	Secondary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis FHA When Administered Concomitantly With RotaTeq™, Predose 1
Measure Description	GMT of pertussis FHA in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen
Time Frame	Predose (Day 1 of a 3-dose regimen)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**180**	**177**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis FHA When Administered Concomitantly With RotaTeq™, Predose 1		**3.7 (2.7 to 5.1)**

[units: EU/mL] Geometric Mean (95% Confidence Interval)	**4.3 (3.2 to 5.9)**	

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis FHA When Administered Concomitantly With RotaTeq™, Predose 1

16. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis FHA When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen]

Measure Type	Secondary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis FHA When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen
Measure Description	GMT of pertussis FHA in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen
Time Frame	42 days after a 3-dose regimen
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**177**	**176**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis FHA When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [units: EU/mL] Least Squares Mean (95% Confidence Interval)	**74 (67.2 to 81.4)**	**78.8 (71.6 to 86.7)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis FHA When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen

17. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Pertactin When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)]

Measure Type	Secondary

Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Pertactin When Administered Concomitantly With RotaTeq™, Predose 1
Measure Description	GMT of pertussis Pertactin in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen
Time Frame	Predose (Day 1 of a 3-dose regimen)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**180**	**177**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Pertactin When Administered Concomitantly With RotaTeq™, Predose 1 [units: EU/mL] Geometric Mean (95% Confidence Interval)	**1.0 (0.7 to 1.4)**	**1.0 (0.7 to 1.4)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Pertactin When Administered Concomitantly With RotaTeq™, Predose 1

18. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Pertactin When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen]

Measure Type	Secondary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Pertactin When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen
Measure Description	GMT of pertussis Pertactin in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen
Time Frame	42 days after a 3-dose regimen
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa
Number of Participants Analyzed [units: participants]	**177**	**177**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Pertactin When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [units: EU/mL] Geometric Mean (95% Confidence Interval)	**109.6 (96.7 to 124.1)**	**108.2 (93.5 to 125.1)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Pertactin When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen

19. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Toxoid When Administered Concomitantly With RotaTeq™, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)]

Measure Type	Secondary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Toxoid When Administered Concomitantly With RotaTeq™, Predose 1
Measure Description	GMT of pertussis toxoid in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen
Time Frame	Predose (Day 1 of a 3-dose regimen)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa

Number of Participants Analyzed [units: participants]	**180**	**177**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Toxoid When Administered Concomitantly With RotaTeq™, Predose 1 [units: EU/mL] Geometric Mean (95% Confidence Interval)	**0.2 (0.2 to 0.2)**	**0.2 (0.2 to 0.3)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Toxoid When Administered Concomitantly With RotaTeq™, Predose 1

20. Secondary: Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Toxoid When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen]

Measure Type	Secondary
Measure Title	Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Toxoid When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen
Measure Description	GMT of pertussis toxoid in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen
Time Frame	42 days after a 3-dose regimen
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**177**	**176**
Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Toxoid When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen [units: EU/mL] Geometric Mean (95% Confidence Interval)	**28.0 (24.8 to 31.7)**	**28.3 (25.2 to 31.8)**

No statistical analysis provided for Immunogenicity of INFANRIX™ Hexa in Relation to Serum Antibody Levels to Pertussis Toxoid When Administered Concomitantly With RotaTeq™, 42 Days After a 3-dose Regimen

21. Secondary: Serum Neutralizing Antibody (SNA) Response to Serotype G1 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™

Hexa, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)]

Measure Type	Secondary
Measure Title	Serum Neutralizing Antibody (SNA) Response to Serotype G1 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa, Predose 1
Measure Description	GMT of serotype G1 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen
Time Frame	Predose (Day 1 of a 3-dose regimen)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**184**	**182**
Serum Neutralizing Antibody (SNA) Response to Serotype G1 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa, Predose 1 [units: GMT] Geometric Mean (95% Confidence Interval)	**23.3 (19.6 to 27.7)**	**24 (20.3 to 28.4)**

No statistical analysis provided for Serum Neutralizing Antibody (SNA) Response to Serotype G1 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa, Predose 1

22. Secondary: Serum Neutralizing Antibody (SNA) Response to Serotype G1 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa, 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen]

Measure Type	Secondary
Measure Title	Serum Neutralizing Antibody (SNA) Response to Serotype G1 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa, 42 Days After a 3-dose Regimen
Measure Description	GMT of serotype G1 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen
Time Frame	42 days after a 3-dose regimen
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**184**	**183**
Serum Neutralizing Antibody (SNA) Response to Serotype G1 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa, 42 Days After a 3-dose Regimen [units: GMT] Geometric Mean (95% Confidence Interval)	**115.7 (94.2 to 142.1)**	**8.2 (7.2 to 9.3)**

No statistical analysis provided for Serum Neutralizing Antibody (SNA) Response to Serotype G1 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa, 42 Days After a 3-dose Regimen

23. Secondary: Serum Neutralizing Antibody (SNA) Response to Serotype G2 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa, Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)]

Measure Type	Secondary
Measure Title	Serum Neutralizing Antibody (SNA) Response to Serotype G2 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa, Predose 1
Measure Description	GMT of serotype G2 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa at the start of a 3-dose regimen
Time Frame	Predose (Day 1 of a 3-dose regimen)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa
Number of Participants Analyzed [units: participants]	**184**	**181**
Serum Neutralizing Antibody (SNA) Response to Serotype G2 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa, Predose 1 [units: GMT] Geometric Mean (95% Confidence Interval)	**11.7 (10.2 to 13.4)**	**12.2 (10.6 to 14.1)**

No statistical analysis provided for Serum Neutralizing Antibody (SNA) Response to Serotype G2 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa, Predose 1

24. Secondary: Serum Neutralizing Antibody (SNA) Response to Serotype G2 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen]

Measure Type	Secondary
Measure Title	Serum Neutralizing Antibody (SNA) Response to Serotype G2 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen
Measure Description	GMT of serotype G2 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen
Time Frame	42 days after a 3-dose regimen
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa
Number of Participants Analyzed [units: participants]	**184**	**183**
Serum Neutralizing Antibody (SNA) Response to Serotype G2 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen [units: GMT] Geometric Mean (95% Confidence Interval)	**16.6 (14.0 to 19.7)**	**6.1 (5.6 to 6.6)**

No statistical analysis provided for Serum Neutralizing Antibody (SNA) Response to Serotype G2 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen

25. Secondary: Serum Neutralizing Antibody (SNA) Response to Serotype G3 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)]

Measure Type	Secondary
Measure Title	Serum Neutralizing Antibody (SNA) Response to Serotype G3 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1
Measure Description	GMT of serotype G3 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa Predose 1
Time Frame	Predose (Day 1 of a 3-dose regimen)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**184**	**182**
Serum Neutralizing Antibody (SNA) Response to Serotype G3 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1 [units: GMT] Geometric Mean (95% Confidence Interval)	**11.5 (9.7 to 13.6)**	**9.8 (8.5 to 11.3)**

No statistical analysis provided for Serum Neutralizing Antibody (SNA) Response to Serotype G3 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1

26. Secondary: Serum Neutralizing Antibody (SNA) Response to Serotype G3 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen]

Measure Type	Secondary
Measure Title	Serum Neutralizing Antibody (SNA) Response to Serotype G3 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen
Measure Description	GMT of serotype G3 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen
Time Frame	42 days after a 3-dose regimen

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**184**	**183**
Serum Neutralizing Antibody (SNA) Response to Serotype G3 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen [units: GMT] Geometric Mean (95% Confidence Interval)	**28.0 (23.4 to 33.5)**	**5.8 (5.5 to 6.3)**

No statistical analysis provided for Serum Neutralizing Antibody (SNA) Response to Serotype G3 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen

27. Secondary: Serum Neutralizing Antibody (SNA) Response to Serotype G4 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)]

Measure Type	Secondary
Measure Title	Serum Neutralizing Antibody (SNA) Response to Serotype G4 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1
Measure Description	GMT of serotype G4 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa Predose 1
Time Frame	Predose (Day 1 of a 3-dose regimen)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.

Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa
Number of Participants Analyzed [units: participants]	**184**	**182**
Serum Neutralizing Antibody (SNA) Response to Serotype G4 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1 [units: GMT] Geometric Mean (95% Confidence Interval)	**15.5 (12.9 to 18.6)**	**17.9 (15.0 to 21.3)**

No statistical analysis provided for Serum Neutralizing Antibody (SNA) Response to Serotype G4 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1

28. Secondary: Serum Neutralizing Antibody (SNA) Response to Serotype G4 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen]

Measure Type	Secondary
Measure Title	Serum Neutralizing Antibody (SNA) Response to Serotype G4 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen
Measure Description	GMT of serotype G4 in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen
Time Frame	42 days after a 3-dose regimen
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa
Number of Participants Analyzed [units: participants]	**184**	**183**
Serum Neutralizing Antibody (SNA) Response to Serotype G4 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen [units: GMT] Geometric Mean (95% Confidence Interval)	**33.6 (28.6 to 39.6)**	**7.1 (6.5 to 7.7)**

No statistical analysis provided for Serum Neutralizing Antibody (SNA) Response to Serotype G4 in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen

29. Secondary: Serum Neutralizing Antibody (SNA) Response to Serotype P1A in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)]

Measure Type	Secondary
Measure Title	Serum Neutralizing Antibody (SNA) Response to Serotype P1A in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1
Measure Description	GMT of serotype P1A in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa Predose 1
Time Frame	Predose (Day 1 of a 3-dose regimen)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**184**	**181**
Serum Neutralizing Antibody (SNA) Response to Serotype P1A in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1 [units: GMT] Geometric Mean (95% Confidence Interval)	**36.8 (30.9 to 44.0)**	**33.2 (28.1 to 39.3)**

No statistical analysis provided for Serum Neutralizing Antibody (SNA) Response to Serotype P1A in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1

30. Secondary: Serum Neutralizing Antibody (SNA) Response to Serotype P1A in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen]

Measure Type	Secondary
Measure Title	Serum Neutralizing Antibody (SNA) Response to Serotype P1A in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen

Measure Description	GMT of serotype P1A in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen
Time Frame	42 days after a 3-dose regimen
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Number of Participants Analyzed [units: participants]	**184**	**183**
Serum Neutralizing Antibody (SNA) Response to Serotype P1A in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen [units: GMT] Geometric Mean (95% Confidence Interval)	**74.5 (60.7 to 91.3)**	**10.7 (9.2 to 12.4)**

No statistical analysis provided for Serum Neutralizing Antibody (SNA) Response to Serotype P1A in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen

31. Secondary: Serum Neutralizing Antibody (SNA) Response to Serum Anti-rotavirus IgA in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1 [Time Frame: Predose (Day 1 of a 3-dose regimen)]

Measure Type	Secondary
Measure Title	Serum Neutralizing Antibody (SNA) Response to Serum Anti-rotavirus IgA in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1
Measure Description	GMT of serum anti-rotavirus IgA in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa Predose 1
Time Frame	Predose (Day 1 of a 3-dose regimen)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa
Number of Participants Analyzed [units: participants]	**184**	**181**
Serum Neutralizing Antibody (SNA) Response to Serum Anti-rotavirus IgA in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1 [units: GMT] Geometric Mean (95% Confidence Interval)	**0.1 (0.1 to 0.2)**	**0.1 (0.1 to 0.2)**

No statistical analysis provided for Serum Neutralizing Antibody (SNA) Response to Serum Anti-rotavirus IgA in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa Predose 1

32. Secondary: Serum Neutralizing Antibody (SNA) Response to Serum Anti-rotavirus IgA in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen [Time Frame: 42 days after a 3-dose regimen]

Measure Type	Secondary
Measure Title	Serum Neutralizing Antibody (SNA) Response to Serum Anti-rotavirus IgA in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen
Measure Description	GMT of serum anti-rotavirus IgA in subjects receiving RotaTeq™ + INFANRIX™ hexa compared to those receiving placebo + INFANRIX™ hexa 42 days after a 3-dose regimen
Time Frame	42 days after a 3-dose regimen
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol Analysis

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Measured Values

	RotaTeq™ + INFANRIX Hexa	Placebo + INFANRIX Hexa
Number of Participants Analyzed [units: participants]	**184**	**183**

Serum Neutralizing Antibody (SNA) Response to Serum Anti-rotavirus IgA in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen [units: GMT] Geometric Mean (95% Confidence Interval)	**160.0 (119.0 to 215.3)**	**0.2 (0.1 to 0.2)**

No statistical analysis provided for Serum Neutralizing Antibody (SNA) Response to Serum Anti-rotavirus IgA in Patients Receiving RotaTeq™ Concomitantly With INFANRIX™ Hexa 42 Days After a 3-dose Regimen

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Patients in this study were followed for all adverse experiences, for 14 days following each study vaccination.
Additional Description	The number of patients listed in the Adverse Event tables is the number of patients who received study treatment. Although a patient may have had two or more clinical adverse experiences the patient is counted only once in a category. The same patient may appear in different categories.

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Serious Adverse Events

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Total, serious adverse events		
# participants affected / at risk	**3/201 (1.49%)**	**6/202 (2.97%)**
Gastrointestinal disorders		
Abdominal symptom [*1]		
# participants affected / at risk	**0/201 (0.00%)**	**1/202 (0.50%)**
Enteritis [*1]		
# participants affected / at risk	**0/201 (0.00%)**	**1/202 (0.50%)**
Vomiting [*1]		
# participants affected / at risk	**0/201 (0.00%)**	**1/202 (0.50%)**
General disorders		
Pyrexia [*1]		
# participants affected / at risk	**0/201 (0.00%)**	**2/202 (0.99%)**
Infections and infestations		
Gastroenteritis salmonella [*1]		
# participants affected / at risk	**0/201 (0.00%)**	**1/202 (0.50%)**
Pyelonephritis [*1]		
# participants affected / at risk	**0/201 (0.00%)**	**1/202 (0.50%)**

Injury, poisoning and procedural complications		
Accidental overdose * 1		
# participants affected / at risk	**1/201 (0.50%)**	**1/202 (0.50%)**
Concussion * 1		
# participants affected / at risk	**1/201 (0.50%)**	**1/202 (0.50%)**
Head injury * 1		
# participants affected / at risk	**1/201 (0.50%)**	**0/202 (0.00%)**
Metabolism and nutrition disorders		
Dehydration * 1		
# participants affected / at risk	**0/201 (0.00%)**	**1/202 (0.50%)**
Psychiatric disorders		
Crying * 1		
# participants affected / at risk	**0/201 (0.00%)**	**1/202 (0.50%)**
Restlessness * 1		
# participants affected / at risk	**0/201 (0.00%)**	**1/202 (0.50%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA 10.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Patients in this study were followed for all adverse experiences, for 14 days following each study vaccination.
Additional Description	The number of patients listed in the Adverse Event tables is the number of patients who received study treatment. Although a patient may have had two or more clinical adverse experiences the patient is counted only once in a category. The same patient may appear in different categories.

Frequency Threshold

Threshold above which other adverse events are reported	2%

Reporting Groups

	Description
RotaTeq™ + INFANRIX Hexa	Subjects in Group 1 received 3 concomitant doses of RotaTeq™ and INFANRIX™ hexa ≥28 to ≤42 days apart.
Placebo + INFANRIX Hexa	For subjects in Group 2, 3 concomitant doses of placebo were administered concomitantly with INFANRIX™ hexa at intervals of 4 to 6 weeks.

Other Adverse Events

	RotaTeq™ + INFANRIX Hexa	**Placebo + INFANRIX Hexa**
Total, other (not including serious) adverse events		
# participants affected / at risk	**166/201 (82.59%)**	**167/202 (82.67%)**

Eye disorders		
Conjunctivitis [*1]		
# participants affected / at risk	**8/201 (3.98%)**	**3/202 (1.49%)**
Gastrointestinal disorders		
Abdominal pain [*1]		
# participants affected / at risk	**8/201 (3.98%)**	**8/202 (3.96%)**
Diarrhoea [*1]		
# participants affected / at risk	**57/201 (28.36%)**	**65/202 (32.18%)**
Enteritis [*1]		
# participants affected / at risk	**27/201 (13.43%)**	**28/202 (13.86%)**
Flatulence [*1]		
# participants affected / at risk	**9/201 (4.48%)**	**5/202 (2.48%)**
Vomiting [*1]		
# participants affected / at risk	**62/201 (30.85%)**	**48/202 (23.76%)**
General disorders		
Irritability [*1]		
# participants affected / at risk	**7/201 (3.48%)**	**4/202 (1.98%)**
Pain [*1]		
# participants affected / at risk	**4/201 (1.99%)**	**2/202 (0.99%)**
Pyrexia [*1]		
# participants affected / at risk	**106/201 (52.74%)**	**114/202 (56.44%)**
Infections and infestations		
Nasopharyngitis [*1]		
# participants affected / at risk	**8/201 (3.98%)**	**6/202 (2.97%)**
Oral candidiasis [*1]		
# participants affected / at risk	**3/201 (1.49%)**	**5/202 (2.48%)**
Respiratory tract infection [*1]		
# participants affected / at risk	**4/201 (1.99%)**	**3/202 (1.49%)**
Rhinitis [*1]		
# participants affected / at risk	**11/201 (5.47%)**	**17/202 (8.42%)**
Upper respiratory tract infection [*1]		
# participants affected / at risk	**2/201 (1.00%)**	**5/202 (2.48%)**
Viral infection [*1]		
# participants affected / at risk	**5/201 (2.49%)**	**2/202 (0.99%)**
Nervous system disorders		
Somnolence [*1]		
# participants affected / at risk	**7/201 (3.48%)**	**4/202 (1.98%)**
Psychiatric disorders		
Crying [*1]		
# participants affected / at risk	**6/201 (2.99%)**	**7/202 (3.47%)**
Restlessness [*1]		

# participants affected / at risk	**11/201 (5.47%)**	**16/202 (7.92%)**
Respiratory, thoracic and mediastinal disorders		
Cough * 1		
# participants affected / at risk	**8/201 (3.98%)**	**11/202 (5.45%)**
Skin and subcutaneous tissue disorders		
Rash * 1		
# participants affected / at risk	**4/201 (1.99%)**	**1/202 (0.50%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 10.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: Merck agreements may vary with individual investigators, but will not prohibit any investigator from publishing. Merck supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Title: Executive Vice President, Clinical and Quantitative Sciences
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372

Publications of Results:

Ciarlet M, He S, Lai S, Petrecz M, Yuan G, Liu GF, Mikviman E, Heaton PM, Panzer F, Rose T, Koller DY, Van Damme P, Schödel F. Concomitant use of the 3-dose oral pentavalent rotavirus vaccine with a 3-dose primary vaccination course of a diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated polio-Haemophilus influenzae type b vaccine: immunogenicity and reactogenicity. Pediatr Infect Dis J. 2009 Mar;28(3):177-81. doi:

10.1097/INF.0b013e31818c0161.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00258154 History of Changes
Other Study ID Numbers:	V260-010 2005_046
Study First Received:	November 15, 2005
Results First Received:	August 10, 2009
Last Updated:	October 5, 2015
Health Authority:	Belgium: Federal Agency for Medicines and Health Products, FAMHP

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