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A Phase 3b, Randomized, Open-Label Study to Evaluate the Safety and Immunogenicity of Select Travel Vaccines When Administered Concomitantly With MenACWY in Adults

This study has been completed.

Sponsor:	Novartis
Collaborators:	Novartis Vaccines
Information provided by (Responsible Party):	Novartis
ClinicalTrials.gov Identifier:	NCT01466387

Purpose

This study compares the safety and immunogenicity profile of several travel vaccines given alone or concomitantly with MenACWY-CRM to healthy adults.

Condition	Intervention	Phase
Meningococcal Disease Meningococcal Meningitis Typhoid Yellow Fever Rabies Japanese Encephalitis	Biological/Vaccine: Typhoid Vi Polysaccharide Vaccine Biological/Vaccine: Yellow Fever Vaccine Biological/Vaccine: Japanese Encephalitis Vaccine Biological/Vaccine: Rabies Vaccine Biological/Vaccine: MenACWY-CRM Vaccine	Phase 3

Study Type: Interventional
Study Design: Prevention, Parallel Assignment, Open Label, Randomized, Safety/Efficacy Study

Official Title: A Phase 3b, Randomized, Open-Label Study to Evaluate the Safety and Immunogenicity of Select Travel Vaccines When Administered Concomitantly With Novartis Meningococcal ACWY Conjugate Vaccine in Healthy Adults

Further study details as provided by Novartis:

Primary Outcome Measure:

- Geometric Mean Anti-typhoid Vi Antibody Concentrations [Time Frame: Baseline and 1 month postvaccination (day 29).] [Designated as safety issue: No]
  Assessment was made to demonstrate the non-inferiority of the geometric mean anti-typhoid Vi antibody concentrations, 28 days after the vaccination of typhoid Vi polysaccharide (TF) and yellow fever (YF) vaccines given concomitantly with MenACWY-CRM197 to typhoid Vi polysaccharide and yellow fever vaccines given alone in healthy adults aged ≥18 years to ≤60 years.

- Geometric Mean Anti-Yellow Fever Antibody Titer [Time Frame: Baseline and 1 month postvaccination (day 29).] [Designated as safety issue: No]
  Assessment was made to demonstrate the non-inferiority of the geometric mean anti-yellow fever antibody titers, 28 days after the vaccination of typhoid Vi polysaccharide (TF) and yellow fever (YF) vaccines given concomitantly with MenACWY-CRM197 to typhoid Vi polysaccharide and yellow fever vaccines given alone in healthy adults aged ≥18 years to ≤60 years.

- Geometric Mean Anti-Japanese Encephalitis Neutralizing Antibody Titers [Time Frame: Baseline and 1 month post last vaccination (day 57).] [Designated as safety issue: No]
  Assessment was made to demonstrate the non-inferiority of the geometric mean anti-Japanese encephalitis neutralizing antibody titers, 28 days after the vaccination of the second dose of Japanese Encephalitis vaccine and third dose of the rabies virus vaccine given concomitantly with MenACWY-CRM197 or alone in healthy adults aged ≥18 years to ≤60 years.

- Geometric Mean Anti-Rabies Virus Neutralizing Antibody Concentration [Time Frame: Baseline and 1 month post last vaccination (day 57).] [Designated as safety issue: No]
  Assessment was made to demonstrate the non-inferiority of the geometric mean anti-rabies virus neutralizing antibody concentrations, 28 days after the vaccination of the second dose of Japanese encephalitis vaccine and third dose of rabies virus vaccine given concomitantly with MenACWY-CRM197 or alone in healthy adults aged ≥18 years to ≤60 years.

Secondary Outcome Measures:

- Percentages Of Subjects With Anti-YF Neutralizing Antibody Titers ≥ 1/10, 28 Days After The Vaccination Of Typhoid Vi Polysaccharide And Yellow Fever, Concomitantly With MenACWY-CRM197 Or Given Alone [Time Frame: Baseline and 1 month postvaccination (day 29).] [Designated as safety issue: No]
  Immunogenicity was assessed as the percentages of subjects who achieved seroprotection as measured by neutralization test for anti-YF neutralizing antibody titers after the vaccination of typhoid Vi polysaccharide and yellow fever, given alone or concomitantly with MenACWY-CRM197 on day 29. Seroprotection is defined as percentages of subjects who achieved anti-YF neutralizing antibody titers ≥ 1/10 on day 29.

- Percentages Of Subjects With Anti-JE Neutralizing Antibody Titers ≥ 1/10, 28 Days After The Vaccination Of The Last Doses Of Japanese Encephalitis And Rabies, Given Concomitantly With MenACWY-CRM197 Or Alone [Time Frame: Baseline and 1 month post last vaccination (day 57).] [Designated as safety issue: No]
  Immunogenicity was measured as the percentages of subjects who achieved seroprotection as measured by neutralization test for anti-Japanese encephalitis neutralizing antibody titers, 28 days after administration of the second dose of Japanese encephalitis virus vaccine and 28 days after the vaccination of third dose of rabies virus vaccine, given alone or concomitantly with MenACWY-CRM197. Seroprotection is defined as percentages of subjects who achieved anti-JE neutralizing titers ≥ 1/10 on Day 57.

- Percentages Of Subjects With Anti-Rabies Virus Antibody Concentrations ≥ 0.5 IU/mL 28 Days After the Vaccination Of The Last Doses Of Japanese Encephalitis And Rabies Virus, Given Concomitantly With MenACWY-CRM197 Or Alone [Time Frame: Baseline and 1 month post last vaccination (day 57).] [Designated as safety issue: No]
  Immunogenicity was assessed as the percentages of subjects who achieved seroprotection as measured by neutralization test for anti-rabies neutralizing antibody titers, 28 days after administration of the second dose of Japanese encephalitis virus vaccine and 28 days after the vaccination of third dose of rabies virus vaccine, given alone or concomitantly with MenACWY-CRM197. Seroprotection is defined as a subject with a baseline hSBA titer < 1:4, seroresponse was defined as a post-vaccination hSBA titer ≥ 1:8; for a subject with a baseline hSBA titer ≥ 1:4, seroresponse was defined as a post-vaccination hSBA titer of at least 4 times the baseline.

- Geometric Mean hSBA Titers For Meningococcal Serogroups A,C,W,Y 28 Days After The Vaccination Of MenACWY-CRM197 Given Concomitantly With Typhoid Vi Polysaccharide And Yellow Fever Vaccines Alone [Time Frame: Baseline and 1 month postvaccination (day 29).] [Designated as safety issue: No]
  Immunogenicity was assessed by Serum Bactericidal Assay using human complement (hSBA) geometric mean titers (GMTs) for meningococcal serogroups A,C,W,Y 28 days after administration of MenACWY-CRM197 given concomitantly with typhoid Vi polysaccharide and yellow fever vaccines or alone.

- Seroresponse Rate For Meningococcal Serogroups A,C,W,Y 28 Days After Vaccination of MenACWY-CRM197 Given Concomitantly With Typhoid Vi Polysaccharide and Yellow Fever Vaccines or Alone [Time Frame: 1 month postvaccination (day 29)] [Designated as safety issue: No]
  Immunogenicity was assessed by seroresponse rates as measured by human serum bactericidal activity (hSBA) titers for meningococcal serogroups A,C,W,Y 28 days after administration of MenACWY-CRM197 given concomitantly with typhoid Vi polysaccharide and yellow fever vaccines or alone. Seroresponse is defined as a postvaccination hSBA titer ≥1:8; for a subject with a baseline hSBA titer ≥1:4, seroresponse is defined as a postvaccination hSBA titer of at least four times the baseline.

- Geometric Mean hSBA Titers for Meningococcal Serogroups A,C,W,Y 28 Days After the Vaccination of MenACWY-CRM197 Given Concomitantly With Japanese Encephalitis and Rabies Virus Vaccines or Alone [Time Frame: Baseline and 1 month post last vaccination (day 29 or day 57).] [Designated as safety issue: No]
  Immunogenicity was measured by human serum bactericidal activity (hSBA) geometric mean titers (GMTs) for meningococcal serogroups A,C,W,Y 28 days after administration of MenACWY-CRM197 given concomitantly with Japanese encephalitis and rabies virus vaccines or alone.

- Seroresponse Rate for Meningococcal Serogroups A,C,W,Y 28 Days After Vaccination of MenACWY-CRM197 Given Concomitantly With Japanese Encephalitis and Rabies Virus Vaccines or Alone [Time Frame: 1 month post last vaccination (day 29 or day 57)] [Designated as safety issue: No]
  Immunogenicity was assessed by seroresponse rates as measured by human serum bactericidal activity (hSBA) titers for meningococcal serogroups A,C,W,Y 28 days after administration of MenACWY-CRM197 given concomitantly with Japanese encephalitis and rabies virus vaccines or alone. Seroresponse is defined as a subject with a baseline hSBA titer < 1:4, seroresponse was defined as a post-vaccination hSBA titer ≥ 1:8; for a subject with a baseline hSBA titer ≥ 1:4, seroresponse was defined as a postvaccination hSBA titer of at least 4 times the baseline.

- Geometric Mean Rabies Virus Neutralizing Antibody Concentration 28 Days After the Last Vaccination Of Rabies Virus Vaccine Concomitantly Either With Japanese Encephalitis or With Japanese Encephalitis And MenACWY-CRM197 [Time Frame: Baseline and 1 month post last vaccination (day 57).] [Designated as safety issue: No]
  The immunogenicity was assessed in rabies virus vaccine as measured by geometric mean rabies virus neutralizing antibody concentration, 28 days after vaccination of the third dose, when administered alone or concomitantly either with Japanese encephalitis vaccine or with Japanese Encephalitis and MenACWY-CRM197 vaccines.

- Percentages of Subjects With Anti-rabies Virus Concentrations ≥ 0.5 IU/mL, 28 Days After the Last Vaccination of Rabies Virus Vaccine Concomitantly Either With Japanese Encephalitis or With Japanese Encephalitis and MenACWY-CRM197 [Time Frame: Baseline and 1 month post last vaccination (day 57).] [Designated as safety issue: No]

Immunogenicity was measured as the percentages of subjects who achieved seroprotection of anti-rabies virus antibody concentrations 28 days after vaccination of the third dose of rabies virus vaccine, when administered alone or concomitantly either with Japanese encephalitis or with Japanese encephalitis and MenACWY-CRM197 vaccines. Seroprotection is defined as percentages of subjects who achieved anti-rabies virus antibody concentrations ≥ 0.5 IU/mL on day 57.

- Number of Subjects With Adverse Events of Special Interest After Any Vaccination of Japanese Encephalitis and Rabies Virus Vaccines Given Concomitantly With MenACWY-CRM197 or Alone [Time Frame: day 1 to day 57 post last vaccination] [Designated as safety issue: Yes]
  In addition to the AEs and SAEs. Additional AESI were collected from day 1 to day 57 postvaccination in subjects after the vaccination of Japanese encephalitis and rabies virus vaccines given concomitantly with MenACWY-CRM197 or alone.

Enrollment: 552
Study Start Date: November 2011
Study Completion Date: April 2012
Primary Completion Date: April 2012

Arms	Assigned Interventions
Active Comparator: TF+YF Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide and yellow fever vaccine.	Biological/Vaccine: Typhoid Vi Polysaccharide Vaccine One dose of typhoid Vi polysaccharide vaccine. Biological/Vaccine: Yellow Fever Vaccine One dose of yellow fever vaccine.
Active Comparator: TF + YF + MenACWY-CRM197 Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide, yellow fever and meningococcal ACWY conjugate vaccine.	Biological/Vaccine: Typhoid Vi Polysaccharide Vaccine One dose of typhoid Vi polysaccharide vaccine. Biological/Vaccine: Yellow Fever Vaccine One dose of yellow fever vaccine. Biological/Vaccine: MenACWY-CRM Vaccine One dose of MenACWY-CRM vaccine.
Active Comparator: JE + Rabies Subjects ≥18 years to ≤60 years of age who received two doses of Japanese encephalitis and three doses of Rabies vaccine.	Biological/Vaccine: Japanese Encephalitis Vaccine Two doses of Japanese Encephalitis Vaccine. Biological/Vaccine: Rabies Vaccine Three doses of Rabies vaccine.
Active Comparator: JE + Rab + MenACWY-CRM197 Subjects ≥18 years to ≤60 years of age who received two doses of Japanese encephalitis and three doses of Rabies and one dose of meningococcal ACWY conjugate vaccine.	Biological/Vaccine: Japanese Encephalitis Vaccine Two doses of Japanese Encephalitis Vaccine. Biological/Vaccine: Rabies Vaccine Three doses of Rabies vaccine. Biological/Vaccine: MenACWY-CRM Vaccine One dose of MenACWY-CRM vaccine.
Active Comparator: Rabies Subjects ≥18 years to ≤60 years of age who received three doses of Rabies vaccine.	Biological/Vaccine: Rabies Vaccine Three doses of Rabies vaccine.

Active Comparator: MenACWY-CRM197 (Combined) Subjects ≥18 years to ≤60 years of age who received one dose of meningococcal ACWY conjugate vaccine.	Biological/Vaccine: MenACWY-CRM Vaccine One dose of MenACWY-CRM vaccine.

Eligibility

Ages Eligible for Study: 18 Years to 60 Years
Genders Eligible for Study: Both
Accepts healthy volunteers.
Inclusion Criteria:

Female and male subjects who must be healthy and must be:

1. Between 18 and 60 years of age inclusive and who have given their written informed consent;
2. Available for all visits and telephone calls scheduled for the study;
3. In good health as determined by medical history, physical examination and clinical judgment of the investigator;
4. For female subjects, having a negative urine pregnancy test.

Exclusion Criteria:

Individuals not eligible to be enrolled in the study are those:

1. who are breastfeeding;
2. who have a personal history of Neisseria meningitidis infection, typhoid fever, rabies, or any flavivirus infection (e.g., Japanese encephalitis, tick-borne encephalitis, yellow fever, dengue fever, West Nile virus infection);
3. who have been immunized with any of the study vaccines within the last five years as determined by medical history and/or vaccination card;
4. who have received investigational agents or vaccines within 30 days prior to enrollment or who expect to receive an investigational agent or vaccine prior to completion of the study;
5. who have received live licensed vaccines within 30 days and inactive vaccine within 15 days prior to enrollment or for whom receipt of a licensed vaccine is anticipated during the study period.

   (Exception: Influenza vaccine may be administered up to 15 days prior to each study immunization and no less than 15 days after each study immunization);
6. who have received an anti-malaria drug, up to 2 months prior to the study;
7. who have experienced, within the 7 days prior to enrollment, significant acute infection (for example requiring systemic antibiotic treatment or antiviral therapy) or have experienced fever (defined as body temperature ≥ 38°C) within 3 days prior to enrollment;
8. who have any serious acute, chronic or progressive disease such as:
   - history of cancer
   - complicated diabetes mellitus
   - advanced arteriosclerotic disease
   - autoimmune disease
   - HIV infection or AIDS
   - blood dyscrasias
   - congestive heart failure
   - renal failure
   - severe malnutrition (Note: Subjects with mild asthma are eligible for enrollment. Subjects with moderate or severe asthma requiring routine use of inhaled or systemic corticosteroids are not eligible for enrollment);
9. who have epilepsy, any progressive neurological disease or history of Guillain-Barre syndrome;
10. who have a history of anaphylaxis, serious vaccine reactions, or allergy to any vaccine component, including but not limited to latex allergy, egg allergy, antibiotic allergy, chicken proteins or gelatin allergy;
11. who have a known or suspected impairment/alteration of immune function, either congenital or acquired or resulting from (for example):
    - receipt of immunosuppressive therapy within 30 days prior to enrollment (systemic corticosteroids administered for more than 5 days, or in a daily dose > 1 mg/kg/day prednisone or equivalent during any of 30 days prior to enrollment, or cancer chemotherapy);
    - receipt of immunostimulants;
    - receipt of parenteral immunoglobulin preparation, blood products, and/or plasma derivatives within 90 days prior to enrollment and for the full length of the study;
12. who are known to have a bleeding diathesis, or any condition that may be associated with a prolonged bleeding time;
13. who have myasthenia gravis; thyroid or thymic disorders,

14. who have any condition that, in the opinion of the investigator, might interfere with the evaluation of the study objectives;
15. who are part of the study personnel or close family members of those conducting this study.
16. for whom a long-term stay (≥ 1 month) was planned in Africa, Latin America, or Asia.

Contacts and Locations

Locations

Czech Republic

Centrum ockovani a cestovni mediciny (Vaccination and Travel Medicine Centre) Poliklinika II
Bratri Stefanu 895, Hradec Kralove, Czech Republic, 500 03

Germany

University of Munich Georgenstr.5
Muenchen, Germany, 80799

Universitat Rostock, Ernst Heydemann Str 6
Rostock, Germany, 18057

Berliner Centrum Fur Reise und Tropenmedizin
Jaegerstrasse 67-69, Berlin, Germany, 10117

Bernhard Nocht Strasse 74, Hamburg, Germany, 20359

More Information

Responsible Party: Novartis
Study ID Numbers: V59_38
2011-000475-14 [EudraCT Number]
Health Authority: Germany: Paul-Ehrlich-Institute (Federal Institute for Vaccines and Biiomedicines)
Czech Republic: State Institute for Drug Control

Study Results

Participant Flow

Recruitment Details	Subjects were enrolled at 5 sites (Berhard Nocht Institut, Germany, Berliner Centrum fuer Reise, Germany, Universitat Rostock, Germany, University of Munich, Germany, Vacc and Travel Med. Center, Czech Republic)
Pre-Assignment Details	All enrolled subjects were included in the trial.

Arm/Group Title	TF+YF	TF+YF+MenACWY-CRM197	JE+Rabies	JE+Rabies+MenACWY-CRM197	Rabies	MenACWY-CRM197 (Combined)	Total (Not public)
▼ Arm/Group Description	Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide and yellow fever vaccine.	Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide, yellow fever and meningococcal ACWY conjugate vaccine.	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese encephalitis and three doses of Rabies vaccine.	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese encephalitis and three doses of Rabies and one dose of meningococcal ACWY conjugate vaccine.	Subjects ≥18 years to ≤60 years of age who received three doses of Rabies vaccine.	Subjects ≥18 years to ≤60 years of age who received one dose of meningococcal ACWY conjugate vaccine.	
Period Title: **Overall Study**							
Started	101	100	99	101	51	100	552
Completed	100	100	98	99	51	99	547

Not Completed	1	0	1	2	0	1	5
Reason Not Completed							
Adverse Event	0	0	1	1	0	0	2
Lost to Follow-up	0	0	0	0	0	1	1
Protocol Violation	1	0	0	1	0	0	2
(Not Public)	Not Completed = 1 Total from all reasons = 1	Not Completed = 0 Total from all reasons = 0	Not Completed = 1 Total from all reasons = 1	Not Completed = 2 Total from all reasons = 2	Not Completed = 0 Total from all reasons = 0	Not Completed = 1 Total from all reasons = 1	

Baseline Characteristics

Arm/Group Title	TF+YF	TF+YF+MenACWY-CRM197	JE+Rabies	JE+Rabies+MenACWY-CRM197	Rabies	MenACWY-CRM197 (Combined)	Total
Arm/Group Description	Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide and yellow fever vaccine.	Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide, yellow fever and meningococcal ACWY conjugate vaccine.	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese encephalitis and three doses of Rabies vaccine.	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese encephalitis and three doses of Rabies and one dose of meningococcal ACWY conjugate vaccine.	Subjects ≥18 years to ≤60 years of age who received three doses of Rabies vaccine.	Subjects ≥18 years to ≤60 years of age who received one dose of meningococcal ACWY conjugate vaccine.	
Overall Number of Baseline Participants	101	100	99	101	51	100	**552**
Baseline Analysis Population Description [Not specified]							
Age, Continuous units: years Mean (Standard Deviation)	36.5 (10.8)	35.1 (11.0)	35.0 (11.5)	35.0 (11.1)	35.8 (11.6)	36.9 (11.2)	35.7 (11.2)
Gender, Male/Female units: participants Measure Type: Number							
Female	49	44	53	50	21	50	267
Male	52	56	46	51	30	50	285

Outcome Measures

1. Primary Outcome

Title:	Geometric Mean Anti-typhoid Vi Antibody Concentrations
Description:	Assessment was made to demonstrate the non-inferiority of the geometric mean anti-typhoid Vi antibody concentrations, 28 days after the vaccination of typhoid Vi polysaccharide (TF) and yellow fever (YF) vaccines given concomitantly with MenACWY-CRM197 to typhoid Vi polysaccharide and yellow fever vaccines given alone in healthy adults aged ≥18 years to ≤60 years.
Time Frame:	Baseline and 1 month postvaccination (day 29).
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

Analysis was done on the per-protocol (PP) set, ie, the subjects who received the vaccine correctly; provided evaluable serum samples at the relevant time points; and had no major protocol violations as defined prior to analysis.

Arm/Group Title	TF+YF	TF+YF+MenACWY-CRM197
▼ Arm/Group Description:	Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide and yellow fever vaccine.	Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide, yellow fever and meningococcal ACWY conjugate vaccine.
Number of Participants Analyzed	100	99
Geometric Mean (95% Confidence Interval) Units: EI.U/mL		
Day 1 (Typhoid Fever)	6.37 (5.3 to 7.65)	5.6 (4.66 to 6.73)
Day 29 (Typhoid Fever)	134 (104 to 174)	153 (118 to 197)

▼ Statistical Analysis 1 ✔ 1 Note

Statistical Analysis Overview	Comparison Groups	TF+YF, TF+YF+MenACWY-CRM197
	Comments	The primary criterion for immunogenicity (postvaccination, day 29) was that the lower limit of the two-sided 95% confidence interval around the observed ratio of geometric mean concentrations between one dose of typhoid Vi polysaccharide and yellow fever vaccines given concomitantly with MenACWY-CRM197 to typhoid Vi polysaccharide and yellow fever vaccines given alone was greater than 0.5.
	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	GMC TF+YF+MenACWY-CRM/GMC TF+YF.
Statistical Test of Hypothesis	P-Value	NOTE : A Method for the statistical test has been specified, but a P-Value has not been entered.
	Comments	The testing was done by assessing the confidence interval of the ratio.
	Method	ANCOVA
	Comments	The ANCOVA model included vaccine group and center as factors, age as covariate and was adjusted for baseline.
Method of Estimation	Estimation Parameter	Other Estimated Parameter [Ratio of GMC]
	Estimated Value	1.14
	Confidence Interval	(2-Sided) 95%

		0.81 to 1.6
	Estimation Comments	[Not specified]

2. Primary Outcome

Title:	Geometric Mean Anti-Yellow Fever Antibody Titer
Description:	Assessment was made to demonstrate the non-inferiority of the geometric mean anti-yellow fever antibody titers, 28 days after the vaccination of typhoid Vi polysaccharide (TF) and yellow fever (YF) vaccines given concomitantly with MenACWY-CRM197 to typhoid Vi polysaccharide and yellow fever vaccines given alone in healthy adults aged ≥18 years to ≤60 years.
Time Frame:	Baseline and 1 month postvaccination (day 29).
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

Analysis was done on the per-protocol (PP) set, ie, the subjects who received the vaccine correctly; provided evaluable serum samples at the relevant time points; and had no major protocol violations as defined prior to analysis.

Arm/Group Title	TF+YF	TF+YF+MenACWY-CRM197
Arm/Group Description:	Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide and yellow fever vaccine.	Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide, yellow fever and meningococcal ACWY conjugate vaccine.
Number of Participants Analyzed	100	99
Geometric Mean (95% Confidence Interval) Units: Titers		
Day 1 (Yellow Fever)	9.05 (6.82 to 12)	12 (8.68 to 15)
Day 29 (Yellow Fever)	5244 (3929 to 7000)	5022 (3754 to 6717)

Statistical Analysis 1 1 Note

Statistical Analysis Overview	Comparison Groups	TF+YF, TF+YF+MenACWY-CRM197
	Comments	The primary criterion for immunogenicity (postvaccination, day 29) was that the lower limit of the two sided 95% CI around the observed ratio of geometric mean titers between one dose of typhoid Vi polysaccharide and yellow fever vaccines given concomitantly with MenACWY-CRM197 to typhoid Vi polysaccharide and yellow fever vaccines given alone was greater than 0.5.
	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	GMT TF+YF+MenACWY/GMT TF+YF.
Statistical Test of Hypothesis	P-Value	NOTE : A Method for the statistical test has been specified, but a P-Value has not been entered.
	Comments	The testing was done by assessing the confidence interval of the ratio.
	Method	ANCOVA
	Comments	The ANCOVA model included vaccine group and center as factors, age as covariate and was adjusted for baseline.

Method of Estimation	Estimation Parameter	Other Estimated Parameter [Ratio of GMT.]
	Estimated Value	0.96
	Confidence Interval	(2-Sided) 95% 0.65 to 1.41
	Estimation Comments	[Not specified]

3. Primary Outcome

Title:	Geometric Mean Anti-Japanese Encephalitis Neutralizing Antibody Titers
▼ Description:	Assessment was made to demonstrate the non-inferiority of the geometric mean anti-Japanese encephalitis neutralizing antibody titers, 28 days after the vaccination of the second dose of Japanese Encephalitis vaccine and third dose of the rabies virus vaccine given concomitantly with MenACWY-CRM197 or alone in healthy adults aged ≥18 years to ≤60 years.
Time Frame:	Baseline and 1 month post last vaccination (day 57).
Safety Issue?	No

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Analysis was done on the PP set, i.e. the subjects who received the vaccine correctly; provided evaluable serum samples at the relevant time points; and had no major protocol violations as defined prior to analysis.

Arm/Group Title	JE+Rabies	JE+Rab+MenACWY-CRM197
▼ Arm/Group Description:	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese Encephalitis and three doses of Rabies vaccine.	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese Encephalitis and three doses of Rabies vaccine and one dose of Meningococcal conjugate vaccine.
Number of Participants Analyzed	96	97
Geometric Mean (95% Confidence Interval) Units: Titers		
Day 1 (Japanese Encephalitis)	5.61 (5.11 to 6.15)	5.58 (5.09 to 6.12)
Day 57 (Japanese Encephalitis)	183 (151 to 221)	165 (136 to 199)

▼ Statistical Analysis 1 ✔ 1 Note

Statistical Analysis Overview	Comparison Groups	JE+Rabies, JE+Rab+MenACWY-CRM197
	Comments	The primary criterion for immunogenicity (postvaccination, day 57) was that the lower limit of the two sided 95% CI around the observed ratio of geometric mean titers between the second dose of Japanese Encephalitis and third dose of rabies virus vaccines given concomitantly with MenACWY-CRM197 to Japanese Encephalitis and rabies virus vaccines given alone was greater than 0.5.
	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	GMT JE + Rab + MenACWY-CRM/GMT JE + Rab.

Statistical Test of Hypothesis	P-Value	NOTE : A Method for the statistical test has been specified, but a P-Value has not been entered.
	Comments	The testing was done by assessing the confidence interval of the ratio.
	Method	ANCOVA
	Comments	The ANCOVA model included vaccine group and centers as factors, age as covariate and was adjusted for baseline.
Method of Estimation	Estimation Parameter	Other Estimated Parameter [Ratio of GMT]
	Estimated Value	0.9
	Confidence Interval	(2-Sided) 95% 0.7 to 1.16
	Estimation Comments	[Not specified]

4. Primary Outcome

Title:	Geometric Mean Anti-Rabies Virus Neutralizing Antibody Concentration
Description:	Assessment was made to demonstrate the non-inferiority of the geometric mean anti-rabies virus neutralizing antibody concentrations, 28 days after the vaccination of the second dose of Japanese encephalitis vaccine and third dose of rabies virus vaccine given concomitantly with MenACWY-CRM197 or alone in healthy adults aged ≥18 years to ≤60 years.
Time Frame:	Baseline and 1 month post last vaccination (day 57).
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

Analysis was done on the per-protocol (PP) set, i.e. the subjects who received the vaccine correctly; provided evaluable serum samples at the relevant time points; and had no major protocol violations as defined prior to analysis.

Arm/Group Title	JE+Rabies	JE+Rab+MenACWY-CRM197
Arm/Group Description:	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese Encephalitis and three doses of Rabies vaccine.	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese Encephalitis and three doses of Rabies vaccine and one dose of Meningococcal conjugate vaccine.
Number of Participants Analyzed	96	97
Geometric Mean (95% Confidence Interval) Units: IU/mL		
Day 1 (Rabies)	0.056 (0.05 to 0.062)	0.049 (0.044 to 0.054)
Day 57 (Rabies)	12 (9.68 to 14)	11 (8.84 to 13)

Statistical Analysis 1 1 Note

Statistical Analysis Overview	Comparison Groups	JE+Rabies, JE+Rab+MenACWY-CRM197
	Comments	The primary criterion for immunogenicity (postvaccination, day 57) was that the lower limit of the two sided 95% CI around the observed ratio of geometric mean concentrations between the second dose of Japanese encephalitis and third dose of rabies virus vaccines given concomitantly with MenACWY-CRM197 to Japanese encephalitis and rabies virus vaccines given alone was greater than 0.5.

	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	GMC JE + Rab + MenACWY-CRM/GMC JE + Rab.
Statistical Test of Hypothesis	P-Value	NOTE : A Method for the statistical test has been specified, but a P-Value has not been entered.
	Comments	The testing was done by assessing the confidence interval of the ratio.
	Method	ANCOVA
	Comments	The ANCOVA model included vaccine group and center as factors, age as covariate and was adjusted for baseline.
Method of Estimation	Estimation Parameter	Other Estimated Parameter [Ratio of GMC]
	Estimated Value	0.91
	Confidence Interval	(2-Sided) 95% 0.71 to 1.17
	Estimation Comments	[Not specified]

5. Secondary Outcome

Title:	Percentages Of Subjects With Anti-YF Neutralizing Antibody Titers ≥ 1/10, 28 Days After The Vaccination Of Typhoid Vi Polysaccharide And Yellow Fever, Concomitantly With MenACWY-CRM197 Or Given Alone
▼ Description:	Immunogenicity was assessed as the percentages of subjects who achieved seroprotection as measured by neutralization test for anti-YF neutralizing antibody titers after the vaccination of typhoid Vi polysaccharide and yellow fever, given alone or concomitantly with MenACWY-CRM197 on day 29. Seroprotection is defined as percentages of subjects who achieved anti-YF neutralizing antibody titers ≥ 1/10 on day 29.
Time Frame:	Baseline and 1 month postvaccination (day 29).
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Analysis was done on the Modified-Intention to Treat (MITT) set, i.e. the subjects who provided evaluable serum samples whose assay results are available for at least one antigen on baseline and on at least one post-baseline visit.

Arm/Group Title	TF+YF	TF+YF+MenACWY-CRM197
▼ Arm/Group Description:	Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide and yellow fever vaccine.	Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide, yellow fever and meningococcal ACWY conjugate vaccine.
Number of Participants Analyzed	100	100
Number (95% Confidence Interval) Units: Percentages of subjects		
Day 1 (Yellow Fever)	34 (25 to 44)	36 (27 to 46)
Day 29 (Yellow Fever)	100 (96 to 100)	97 (91 to 99)

6. Secondary Outcome

Title:	Percentages Of Subjects With Anti-JE Neutralizing Antibody Titers ≥ 1/10, 28 Days After The Vaccination Of The Last Doses Of Japanese Encephalitis And Rabies, Given Concomitantly With MenACWY-CRM197 Or Alone
▼ Description:	Immunogenicity was measured as the percentages of subjects who achieved seroprotection as measured by neutralization test for anti-Japanese encephalitis neutralizing antibody titers, 28 days after administration of the second dose of Japanese encephalitis virus vaccine and 28 days after the vaccination of third dose of rabies virus vaccine, given alone or concomitantly with MenACWY-CRM197. Seroprotection is defined as percentages of subjects who achieved anti-JE neutralizing titers ≥ 1/10 on Day 57.
Time Frame:	Baseline and 1 month post last vaccination (day 57).
Safety Issue?	No

▼ Outcome Measure Data ✓

▼ Analysis Population Description

The analysis was done on the MITT data set.

Arm/Group Title	JE+Rabies	JE+Rabies+MenACWY-CRM197
▼ Arm/Group Description:	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese Encephalitis and three doses of Rabies vaccine.	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese Encephalitis and three doses of Rabies and one dose of meningococcal ACWY conjugate vaccine.
Number of Participants Analyzed	98	99
Number (95% Confidence Interval) Units: Percentages of subects		
Day 1 (Japanese Encephalitis)	3 (1 to 9)	4 (1 to 10)
Day 57 (Japanese Encephalitis)	99 (94 to 100)	98 (93 to 100)

7. Secondary Outcome

Title:	Percentages Of Subjects With Anti-Rabies Virus Antibody Concentrations ≥ 0.5 IU/mL 28 Days After the Vaccination Of The Last Doses Of Japanese Encephalitis And Rabies Virus, Given Concomitantly With MenACWY-CRM197 Or Alone
▼ Description:	Immunogenicity was assessed as the percentages of subjects who achieved seroprotection as measured by neutralization test for anti-rabies neutralizing antibody titers, 28 days after administration of the second dose of Japanese encephalitis virus vaccine and 28 days after the vaccination of third dose of rabies virus vaccine, given alone or concomitantly with MenACWY-CRM197. Seroprotection is defined as a subject with a baseline hSBA titer < 1:4, seroresponse was defined as a post-vaccination hSBA titer ≥ 1:8; for a subject with a baseline hSBA titer ≥ 1:4, seroresponse was defined as a post-vaccination hSBA titer of at least 4 times the baseline.
Time Frame:	Baseline and 1 month post last vaccination (day 57).
Safety Issue?	No

▼ Outcome Measure Data ✓

▼ Analysis Population Description

Analysis was done on the MITT data set.

Arm/Group Title	JE+Rabies	JE+Rabies+MenACWY-CRM197
▼ Arm/Group Description:	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese Encephalitis and three doses of Rabies vaccine.	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese Encephalitis and three doses of Rabies vaccine and one dose

		of Meningococcal conjugate vaccine.
Number of Participants Analyzed	98	99
Number (95% Confidence Interval) Units: Percentages of subjects		
Day 1 (Rabies)	3 (1 to 9)	1 (0.026 to 5)
Day 57 (Rabies)	100 (96 to 100)	100 (96 to 100)

8. Secondary Outcome

Title:	Geometric Mean hSBA Titers For Meningococcal Serogroups A,C,W,Y 28 Days After The Vaccination Of MenACWY-CRM197 Given Concomitantly With Typhoid Vi Polysaccharide And Yellow Fever Vaccines Alone
▼ Description:	Immunogenicity was assessed by Serum Bactericidal Assay using human complement (hSBA) geometric mean titers (GMTs) for meningococcal serogroups A,C,W,Y 28 days after administration of MenACWY-CRM197 given concomitantly with typhoid Vi polysaccharide and yellow fever vaccines or alone.
Time Frame:	Baseline and 1 month postvaccination (day 29).
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Analysis was done on the MITT data set.

Arm/Group Title	MenACWY-CRM197 (Combined)	TF+YF+MenACWY-CRM197
▼ Arm/Group Description:	Subjects ≥18 years to ≤60 years of age who received one dose of meningococcal ACWY conjugate vaccine.	Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide, yellow fever and meningococcal ACWY conjugate vaccine.
Number of Participants Analyzed	99	100
Geometric Mean (95%		

Confidence Interval) Units: titers		
Serogroup A (Day 1)	2.94 (2.43 to 3.56)	2.78 (2.3 to 3.36)
Serogroup A (Day 29)	65 (44 to 95)	62 (42 to 90)
Serogroup C (Day 1)	7.94 (5.94 to 11)	7.03 (5.27 to 9.38)
Serogroup C (Day 29)	49 (35 to 70)	54 (38 to 76)
Serogroup W (Day 1)	50 (35 to 71)	32 (22 to 45)
Serogroup W (Day 29)	129 (94 to 177)	211 (154 to 290)
Serogroup Y (Day 1)	7.61 (5.71 to 10)	7.76 (5.83 to 10)
Serogroup Y (Day 29)	89 (62 to 129)	78 (54 to 113)

9. Secondary Outcome

Title:	Seroresponse Rate For Meningococcal Serogroups A,C,W,Y 28 Days After Vaccination of MenACWY-CRM197 Given Concomitantly With Typhoid Vi Polysaccharide and Yellow Fever Vaccines or Alone
▼ Description:	Immunogenicity was assessed by seroresponse rates as measured by human serum bactericidal activity (hSBA) titers for meningococcal serogroups A,C,W,Y 28 days after administration of MenACWY-CRM197 given concomitantly with typhoid Vi polysaccharide and yellow fever vaccines or alone. Seroresponse is defined as a postvaccination hSBA titer ≥1:8; for a subject with a baseline hSBA titer ≥1:4, seroresponse is defined as a postvaccination hSBA titer of at least four times the baseline.
Time Frame:	1 month postvaccination (day 29)
Safety Issue?	No

▼ Outcome Measure Data ✓

▼ Analysis Population Description

The analysis was done on the MITT data set.

Arm/Group Title	TF + YF + MenACWY-CRM197	MenACWY-CRM197 (Combined)

▼ Arm/Group Description:	Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide, yellow fever and meningococcal ACWY conjugate vaccine.	Subjects ≥18 years to ≤60 years of age who received one dose of meningococcal ACWY conjugate vaccine.
Number of Participants Analyzed	100	99
Number (95% Confidence Interval) Units: Percentages of subjects		
Serogroup A (Overall Seroresponse)	72 (62 to 81)	71 (61 to 79)
Serogroup C (Overall Seroresponse)	48 (38 to 58)	47 (37 to 58)
Serogroup W (Overall Seroresponse)	51 (40 to 61)	30 (21 to 40)
Serogroup Y (Overall Seroresponse)	63 (53 to 72)	66 (55 to 75)

10. Secondary Outcome

Title:	Geometric Mean hSBA Titers for Meningococcal Serogroups A,C,W,Y 28 Days After the Vaccination of MenACWY-CRM197 Given Concomitantly With Japanese Encephalitis and Rabies Virus Vaccines or Alone
▼ Description:	Immunogenicity was measured by human serum bactericidal activity (hSBA) geometric mean titers (GMTs) for meningococcal serogroups A,C,W,Y 28 days after administration of MenACWY-CRM197 given concomitantly with Japanese encephalitis and rabies virus vaccines or alone.
Time Frame:	Baseline and 1 month post last vaccination (day 29 or day 57).
Safety Issue?	No

▼ Outcome Measure Data ✔

▼ Analysis Population Description

The analysis was done on the MITT data set.

Arm/Group Title	JE + Rab + MenACWY-CRM197	MenACWY-CRM197 (Combined)
▼ Arm/Group Description:	Subjects ≥18 years to ≤60 years of age who received two doses of	Subjects ≥18 years to ≤60 years of age who received one dose of

	Japanese Encephalitis and three doses of Rabies and one dose of meningococcal ACWY conjugate vaccine.	meningococcal ACWY conjugate vaccine.
Number of Participants Analyzed	99	99
Geometric Mean (95% Confidence Interval) Units: titers		
Serogroup A (Day 1)	3.21 (2.65 to 3.88)	2.94 (2.43 to 3.56)
Serogroup A (Day 29 or Day 57)	32 (22 to 47)	65 (44 to 95)
Serogroup C (Day 1)	8.81 (6.59 to 12)	7.94 (5.94 to 11)
Serogroup C (Day 29 or Day 57)	44 (31 to 62)	49 (35 to 70)
Serogroup W (Day 1)	54 (38 to 77)	50 (35 to 71)
Serogroup W (Day 29 or Day 57)	119 (87 to 164)	129 (94 to 177)
Serogroup Y (Day 1)	8.11 (6.08 to 11)	7.61 (5.71 to 10)
Serogroup Y (Day 29 or Day 57)	55 (38 to 80)	89 (62 to 129)

11. Secondary Outcome

Title:	Seroresponse Rate for Meningococcal Serogroups A,C,W,Y 28 Days After Vaccination of MenACWY-CRM197 Given Concomitantly With Japanese Encephalitis and Rabies Virus Vaccines or Alone
▼ Description:	Immunogenicity was assessed by seroresponse rates as measured by human serum bactericidal activity (hSBA) titers for meningococcal serogroups A,C,W,Y 28 days after administration of MenACWY-CRM197 given concomitantly with Japanese encephalitis and rabies virus vaccines or alone. Seroresponse is defined as a subject with a baseline hSBA titer < 1:4, seroresponse was defined as a post-vaccination hSBA titer ≥ 1:8; for a subject with a baseline hSBA titer ≥ 1:4, seroresponse was defined as a postvaccination hSBA titer of at least 4 times the baseline.
Time Frame:	1 month post last vaccination (day 29 or day 57)
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

The analysis was done on the MITT data set.

Arm/Group Title	JE + Rab + MenACWY-CRM197	MenACWY-CRM197 (Combined)
▼ Arm/Group Description:	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese Encephalitis and three doses of Rabies and one dose of meningococcal ACWY conjugate vaccine.	Subjects ≥18 years to ≤60 years of age who received one dose of meningococcal ACWY conjugate vaccine.
Number of Participants Analyzed	99	99
Number (95% Confidence Interval) Units: Percentages of subjects		
Serogroup A (Overall Seroresponse)	60 (49 to 69)	71 (61 to 79)
Serogroup C (Overall Seroresponse)	43 (33 to 54)	47 (37 to 58)
Serogroup W (Overall Seroresponse)	32 (23 to 42)	30 (21 to 40)
Serogroup Y (Overall Seroresponse)	56 (45 to 66)	66 (55 to 75)

12. Secondary Outcome

Title:	Geometric Mean Rabies Virus Neutralizing Antibody Concentration 28 Days After the Last Vaccination Of Rabies Virus Vaccine Concomitantly Either With Japanese Encephalitis or With Japanese Encephalitis And MenACWY-CRM197
▼ Description:	The immunogenicity was assessed in rabies virus vaccine as measured by geometric mean rabies virus neutralizing antibody concentration, 28 days after vaccination of the third dose, when administered alone or concomitantly either with Japanese encephalitis vaccine or with Japanese Encephalitis and MenACWY-CRM197 vaccines.
Time Frame:	Baseline and 1 month post last vaccination (day 57).
Safety Issue?	No

▼ Outcome Measure Data ✔

▼ Analysis Population Description

The analysis was done on the MITT data set.

Arm/Group Title	JE + Rabies + MenACWY-CRM197	JE + Rabies	Rabies

▼ Arm/Group Description:	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese Encephalitis and three doses of Rabies and one dose of meningococcal ACWY conjugate vaccine.	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese Encephalitis and three doses of rabies vaccine.	Subjects ≥18 years to ≤60 years of age who received three doses of Rabies vaccine
Number of Participants Analyzed	99	98	51
Geometric Mean (95% Confidence Interval) Units: IU/mL			
Day 1 (Rabies)	0.051 (0.044 to 0.059)	0.057 (0.049 to 0.065)	0.068 (0.056 to 0.082)
Day 57 (Rabies)	11 (8.84 to 13)	11 (9.49 to 14)	8.97 (6.98 to 12)

13. Secondary Outcome

Title:	Percentages of Subjects With Anti-rabies Virus Concentrations ≥ 0.5 IU/mL, 28 Days After the Last Vaccination of Rabies Virus Vaccine Concomitantly Either With Japanese Encephalitis or With Japanese Encephalitis and MenACWY-CRM197
▼ Description:	Immunogenicity was measured as the percentages of subjects who achieved seroprotection of anti-rabies virus antibody concentrations 28 days after vaccination of the third dose of rabies virus vaccine, when administered alone or concomitantly either with Japanese encephalitis or with Japanese encephalitis and MenACWY-CRM197 vaccines. Seroprotection is defined as percentages of subjects who achieved anti-rabies virus antibody concentrations ≥ 0.5 IU/mL on day 57.
Time Frame:	Baseline and 1 month post last vaccination (day 57).
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

The analysis was done on the MITT data set.

Arm/Group Title	JE + Rabies + MenACWY-CRM197	JE + Rabies	Rabies
▼ Arm/Group Description:	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese Encephalitis and three doses of Rabies and one dose of meningococcal ACWY conjugate vaccine.	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese Encephalitis and three doses of Rabies vaccine.	Subjects ≥18 years to ≤60 yars of age who received three doses of Rabies vaccine.
Number of Participants	99	98	51

Analyzed			
Number (95% Confidence Interval) Units: Percentages of subjects			
Day 1 (Rabies)	1 (0.026 to 5)	3 (1 to 9)	8 (2 to 19)
Day 57 (Rabies)	100 (96 to 100)	100 (96 to 100)	100 (93 to 100)

14. Secondary Outcome

Title:	Number of Subjects With Adverse Events of Special Interest After Any Vaccination of Japanese Encephalitis and Rabies Virus Vaccines Given Concomitantly With MenACWY-CRM197 or Alone
▼ Description:	In addition to the AEs and SAEs. Additional AESI were collected from day 1 to day 57 postvaccination in subjects after the vaccination of Japanese encephalitis and rabies virus vaccines given concomitantly with MenACWY-CRM197 or alone.
Time Frame:	day 1 to day 57 post last vaccination
Safety Issue?	Yes

▼ Outcome Measure Data

▼ Analysis Population Description

Analysis was done on the safety data set, i.e. the subjects in the exposed population who provided postvaccination safety data.

Arm/Group Title	JE + Rabies + MenACWY-CRM197	JE + Rabies
▼ Arm/Group Description:	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese Encephalitis and three doses of Rabies and one dose of meningococcal ACWY conjugate vaccine.	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese Encephalitis and three doses of Rabies vaccine.
Number of Participants Analyzed	101	99
Measure Type: Number		

Units: subjects		
Injection site erythema	0	1
Hypersensitivity	1	0
Paresthesia	0	1
Erythema	1	0
Pruritus	1	1
Hot flush	1	0

Adverse Events

Time Frame	day 1 to day 29 (one month postvaccination); day 1 to day 57 (one month post last vaccination)
Additional Description	AEs and SAEs were collected from day 1-29 for subjects vaccinated with typhoid Vi polysaccharide+YF +MenACWY-CRM197 or alone, from day 1-57 vaccinated with JE+rabies virus+MenACWY-CRM197 or alone and who received rabies vaccine alone.
Source Vocabulary Name	MedDRA
Assessment Type	[Not specified] NOTE : An Assessment Type for Table Default has not been specified.

Arm/Group Title	TF+YF	TF+YF+MenACWY-CRM197	JE+Rabies	JE+Rabies+MenACWY-CRM197	Rabies	MenACWY-CRM197 (Combined)
Arm/Group Description	Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide and yellow fever vaccine.	Subjects ≥18 years to ≤60 years of age who received one dose of typhoid Vi polysaccharide, yellow fever and meningococcal ACWY conjugate vaccine.	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese encephalitis and three doses of Rabies vaccine.	Subjects ≥18 years to ≤60 years of age who received two doses of Japanese encephalitis and three doses of Rabies and one dose of meningococcal ACWY conjugate vaccine.	Subjects ≥18 years to ≤60 years of age who received three doses of Rabies vaccine.	Subjects ≥18 years to ≤60 years of age who received one dose of meningococcal ACWY conjugate vaccine.

Serious Adverse Events

		TF+YF	TF+YF+MenACWY-CRM197	JE+Rabies	JE+Rabies+MenACWY-CRM197	Rabies	MenACWY-CRM197 (Combined)
		Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total		0/101 (0%)	0/100 (0%)	1/99 (1.01%)	1/101 (0.99%)	0/51 (0%)	0/100 (0%)
Injury, poi...	Injury [A]	0/101 (0%)	0/100 (0%)	1/99 (1.01%)	0/101 (0%)	0/51 (0%)	0/100 (0%)
Musculoskel...	Intervertebral disc protrusion [A]	0/101 (0%)	0/100 (0%)	0/99 (0%)	1/101 (0.99%)	0/51 (0%)	0/100 (0%)

Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%

		TF+YF	TF+YF+MenACWY-CRM197	JE+Rabies	JE+Rabies+MenACWY-CRM197	Rabies	MenACWY-CRM197 (Combined)
		Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total		27/101 (26.73%)	30/100 (30%)	23/99 (23.23%)	22/101 (21.78%)	9/51 (17.65%)	9/100 (9%)
General dis...	Injection site pain [A]	12/101 (11.88%)	8/100 (8%)	6/99 (6.06%)	4/101 (3.96%)	2/51 (3.92%)	2/100 (2%)
General dis...	Headache [A]	7/101 (6.93%)	10/100 (10%)	9/99 (9.09%)	5/101 (4.95%)	5/51 (9.8%)	4/100 (4%)
General dis...	Influenza like illness [A]	5/101 (4.95%)	9/100 (9%)	5/99 (5.05%)	6/101 (5.94%)	0/51 (0%)	2/100 (2%)
Infections ...	Nasopharyngitis [A]	3/101 (2.97%)	3/100 (3%)	3/99 (3.03%)	7/101 (6.93%)	2/51 (3.92%)	1/100 (1%)

Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.
There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

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