Trial record **2 of 2** for: H01_04TP
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Safety and Immunogenicity of Three Formulations of Vi-CRM197 Vaccine Against S. Typhi in Adults (18-40 Years Old)

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT01193907

First received: September 1, 2010
Last updated: December 16, 2013
Last verified: December 2013
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: March 6, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Single Blind (Subject); Primary Purpose: Prevention
Condition:	Typhoid Fever
Interventions:	Biological: NVGH Vi-CRM197 12.5 mcg Biological: NVGH Vi-CRM197 5.0 mcg

	Biological: NVGH Vi-CRM197 1.25 mcg Biological: Vi-polysaccharide vaccine

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
Date of first enrollment: 04 OCT 10 Date of last visit: 18 NOV 10

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
NVGH Vi-CRM197 12.5 Mcg	1 dose of 0.5 mL containing 12.5 mcg of Vi-CRM
NVGH Vi-CRM197 5.0 Mcg	1 dose of 0.5 mL containing 5.0 mcg of Vi-CRM
NVGH Vi-CRM197 1.25 Mcg	1 dose of 0.5 mL containing 1.25 mcg of Vi-CRM
Typherix	1 dose of 0.5 mL containing 25 mcg of Vi-PS

Participant Flow: Overall Study

	NVGH Vi-CRM197 12.5 Mcg	NVGH Vi-CRM197 5.0 Mcg	NVGH Vi-CRM197 1.25 Mcg	Typherix
STARTED	**22**	**22**	**22**	**22**
COMPLETED	**21**	**22**	**22**	**21**
NOT COMPLETED	**1**	**0**	**0**	**1**

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
NVGH Vi-CRM197 12.5 Mcg	1 dose of 0.5 mL containing 12.5 mcg of Vi-CRM
NVGH Vi-CRM197 5.0 Mcg	1 dose of 0.5 mL containing 5.0 mcg of Vi-CRM
NVGH Vi-CRM197 1.25 Mcg	1 dose of 0.5 mL containing 1.25 mcg of Vi-CRM
Typherix	1 dose of 0.5 mL containing 25 mcg of Vi-PS
Total	Total of all reporting groups

Baseline Measures

	NVGH Vi-CRM197 12.5 Mcg	NVGH Vi-CRM197 5.0 Mcg	NVGH Vi-CRM197 1.25 Mcg	Typherix	Total
Overall Participants Analyzed [Units: Participants]	**22**	**22**	**22**	**22**	**88**
Age [Units: Participants]					
<=18 years	**0**	**0**	**0**	**0**	**0**
Between 18 and 65 years	**22**	**22**	**22**	**22**	**88**
>=65 years	**0**	**0**	**0**	**0**	**0**
	24.3 (4.9)	**24.3 (5.4)**	**24.0 (5.7)**	**23.8 (5.5)**	**24.1 (5.3)**

Age [Units: Years] Mean (Standard Deviation)					
Gender [Units: Participants]					
Female	**14**	**15**	**17**	**15**	**61**
Male	**8**	**7**	**5**	**7**	**27**
Region of Enrollment [Units: Participants]					
Belgium	**22**	**22**	**22**	**22**	**88**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Subjects Reporting Any Post Immunization Reactions [Time Frame: During the 7-day period after vaccination]

Measure Type	Primary
Measure Title	Number of Subjects Reporting Any Post Immunization Reactions
Measure Description	Solicited reactions collected during the 7-day period after vaccination are pain, erythema, induration, chills, malaise, myalgia, headache, arthralgia and fatigue
Time Frame	During the 7-day period after vaccination
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.
No text entered.

Reporting Groups

	Description
NVGH Vi-CRM197 12.5 Mcg	1 dose of 0.5 mL containing 12.5 mcg of Vi-CRM
NVGH Vi-CRM197 5.0 Mcg	1 dose of 0.5 mL containing 5.0 mcg of Vi-CRM
NVGH Vi-CRM197 1.25 Mcg	1 dose of 0.5 mL containing 1.25 mcg of Vi-CRM
Typherix	1 dose of 0.5 mL containing 25 mcg of Vi-PS

Measured Values

	NVGH Vi-CRM197 12.5 Mcg	NVGH Vi-CRM197 5.0 Mcg	NVGH Vi-CRM197 1.25 Mcg	Typherix
Participants Analyzed [Units: Participants]	**21**	**22**	**22**	**22**
Number of Subjects Reporting Any Post Immunization Reactions [Units: Participants]	**18**	**19**	**22**	**16**

No statistical analysis provided for Number of Subjects Reporting Any Post Immunization Reactions

2. Primary: Number of Subjects Reporting Adverse Events [Time Frame: During the 28-day period after vaccination]

Measure Type	Primary
Measure Title	Number of Subjects Reporting Adverse Events
Measure Description	No text entered.
Time Frame	During the 28-day period after vaccination
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.
No text entered.

Reporting Groups

	Description
NVGH Vi-CRM197 12.5 Mcg	1 dose of 0.5 mL containing 12.5 mcg of Vi-CRM
NVGH Vi-CRM197 5.0 Mcg	1 dose of 0.5 mL containing 5.0 mcg of Vi-CRM
NVGH Vi-CRM197 1.25 Mcg	1 dose of 0.5 mL containing 1.25 mcg of Vi-CRM
Typherix	1 dose of 0.5 mL containing 25 mcg of Vi-PS

Measured Values

	NVGH Vi-CRM197 12.5 Mcg	**NVGH Vi-CRM197 5.0 Mcg**	**NVGH Vi-CRM197 1.25 Mcg**	**Typherix**
Participants Analyzed [Units: Participants]	**21**	**22**	**22**	**22**
Number of Subjects Reporting Adverse Events [Units: Participants]	**11**	**16**	**18**	**15**

No statistical analysis provided for Number of Subjects Reporting Adverse Events

3. Primary: Anti-Vi ELISA (Enzyme Linked Immunosorbent Assay) Geometric Mean Concentration (GMC) [Time Frame: At 28 days after vaccination]

Measure Type	Primary

Measure Title	Anti-Vi ELISA (Enzyme Linked Immunosorbent Assay) Geometric Mean Concentration (GMC)
Measure Description	No text entered.
Time Frame	At 28 days after vaccination
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.
No text entered.

Reporting Groups

	Description
NVGH Vi-CRM197 12.5 Mcg	1 dose of 0.5 mL containing 12.5 mcg of Vi-CRM
NVGH Vi-CRM197 5.0 Mcg	1 dose of 0.5 mL containing 5.0 mcg of Vi-CRM
NVGH Vi-CRM197 1.25 Mcg	1 dose of 0.5 mL containing 1.25 mcg of Vi-CRM
Typherix	1 dose of 0.5 mL containing 25 mcg of Vi-PS

Measured Values

	NVGH Vi-CRM197 12.5 Mcg	**NVGH Vi-CRM197 5.0 Mcg**	**NVGH Vi-CRM197 1.25 Mcg**	**Typherix**
Participants Analyzed [Units: Participants]	**21**	**21**	**19**	**20**
Anti-Vi ELISA (Enzyme Linked Immunosorbent Assay) Geometric Mean Concentration (GMC) [Units: GMC] Mean (95% Confidence Interval)	**192** **(129 to 286)**	**111** **(75 to 165)**	**63** **(41 to 95)**	**37** **(24 to 55)**

No statistical analysis provided for Anti-Vi ELISA (Enzyme Linked Immunosorbent Assay) Geometric Mean Concentration (GMC)

4. Primary: Percentage of Subjects With at Least 4-fold Increase in Anti-Vi ELISA Titer [Time Frame: At 28 days after vaccination]

Measure Type	Primary
Measure Title	Percentage of Subjects With at Least 4-fold Increase in Anti-Vi ELISA Titer
Measure Description	No text entered.
Time Frame	At 28 days after vaccination
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.
No text entered.

Reporting Groups

	Description
NVGH Vi-CRM197 12.5 Mcg	1 dose of 0.5 mL containing 12.5 mcg of Vi-CRM
NVGH Vi-CRM197 5.0 Mcg	1 dose of 0.5 mL containing 5.0 mcg of Vi-CRM
NVGH Vi-CRM197 1.25 Mcg	1 dose of 0.5 mL containing 1.25 mcg of Vi-CRM
Typherix	1 dose of 0.5 mL containing 25 mcg of Vi-PS

Measured Values

	NVGH Vi-CRM197 12.5 Mcg	**NVGH Vi-CRM197 5.0 Mcg**	**NVGH Vi-CRM197 1.25 Mcg**	**Typherix**
Participants Analyzed [Units: Participants]	**21**	**21**	**19**	**20**

Percentage of Subjects With at Least 4-fold Increase in Anti-Vi ELISA Titer [Units: Percentage of subjects] Number (95% Confidence Interval)	**100** **(84 to 100)**	**100** **(84 to 100)**	**95** **(74 to 100)**	**95** **(75 to 100)**

No statistical analysis provided for Percentage of Subjects With at Least 4-fold Increase in Anti-Vi ELISA Titer

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
NVGH Vi-CRM197 12.5 Mcg	1 dose of 0.5 mL containing 12.5 mcg of Vi-CRM
NVGH Vi-CRM197 5.0 Mcg	1 dose of 0.5 mL containing 5.0 mcg of Vi-CRM
NVGH Vi-CRM197 1.25 Mcg	1 dose of 0.5 mL containing 1.25 mcg of Vi-CRM
Typherix	1 dose of 0.5 mL containing 25 mcg of Vi-PS

Serious Adverse Events

	NVGH Vi-CRM197 12.5 Mcg	NVGH Vi-CRM197 5.0 Mcg	NVGH Vi-CRM197 1.25 Mcg	Typherix
Total, serious adverse events				
# participants affected / at risk	**0/21 (0.00%)**	**0/22 (0.00%)**	**0/22 (0.00%)**	**0/22 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
NVGH Vi-CRM197 12.5 Mcg	1 dose of 0.5 mL containing 12.5 mcg of Vi-CRM
NVGH Vi-CRM197 5.0 Mcg	1 dose of 0.5 mL containing 5.0 mcg of Vi-CRM
NVGH Vi-CRM197 1.25 Mcg	1 dose of 0.5 mL containing 1.25 mcg of Vi-CRM
Typherix	1 dose of 0.5 mL containing 25 mcg of Vi-PS

Other Adverse Events

	NVGH Vi-CRM197 12.5 Mcg	NVGH Vi-CRM197 5.0 Mcg	NVGH Vi-CRM197 1.25 Mcg	Typherix
Total, other (not including serious) adverse events				
# participants affected / at risk	**19/21 (90.48%)**	**19/22 (86.36%)**	**22/22 (100.00%)**	**19/22 (86.36%)**
Gastrointestinal disorders				
diarrhoea *				
# participants affected / at risk	**1/21 (4.76%)**	**3/22 (13.64%)**	**5/22 (22.73%)**	**1/22 (4.55%)**
nausea *				
# participants affected / at risk	**0/21 (0.00%)**	**4/22 (18.18%)**	**2/22 (9.09%)**	**0/22 (0.00%)**

General disorders				
chills †				
# participants affected / at risk	**1/21 (4.76%)**	**2/22 (9.09%)**	**2/22 (9.09%)**	**2/22 (9.09%)**
Fatigue †				
# participants affected / at risk	**7/21 (33.33%)**	**11/22 (50.00%)**	**8/22 (36.36%)**	**7/22 (31.82%)**
injection site erythema †				
# participants affected / at risk	**3/21 (14.29%)**	**2/22 (9.09%)**	**2/22 (9.09%)**	**0/22 (0.00%)**
injection site induration †				
# participants affected / at risk	**3/21 (14.29%)**	**4/22 (18.18%)**	**3/22 (13.64%)**	**2/22 (9.09%)**
injection site pain †				
# participants affected / at risk	**17/21 (80.95%)**	**16/22 (72.73%)**	**21/22 (95.45%)**	**9/22 (40.91%)**
malaise †				
# participants affected / at risk	**4/21 (19.05%)**	**4/22 (18.18%)**	**5/22 (22.73%)**	**4/22 (18.18%)**
Infections and infestations				
nasopharingitis *				
# participants affected / at risk	**4/21 (19.05%)**	**9/22 (40.91%)**	**5/22 (22.73%)**	**5/22 (22.73%)**
viral URTI *				
# participants affected / at risk	**2/21 (9.52%)**	**0/22 (0.00%)**	**0/22 (0.00%)**	**0/22 (0.00%)**
Musculoskeletal and connective tissue disorders				
arthralgia †				
# participants affected / at risk	**2/21 (9.52%)**	**0/22 (0.00%)**	**0/22 (0.00%)**	**0/22 (0.00%)**
myalgia †				
# participants affected / at risk	**5/21 (23.81%)**	**4/22 (18.18%)**	**4/22 (18.18%)**	**3/22 (13.64%)**
Nervous system disorders				
headache †				
# participants affected / at risk	**11/21 (52.38%)**	**11/22 (50.00%)**	**12/22 (54.55%)**	**10/22 (45.45%)**
Skin and subcutaneous tissue disorders				

rash *				
# participants affected / at risk	**0/21 (0.00%)**	**0/22 (0.00%)**	**2/22 (9.09%)**	**0/22 (0.00%)**

† Events were collected by systematic assessment
* Events were collected by non-systematic assessment

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: In the event that no publication of the Study results has been made by NVGH within twelve (12) months of Study

database lock and no proposed publication is under discussion by the publication committee, Principal Investigator may publish its own Study results.

Results Point of Contact:

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Publications of Results:

van Damme P, Kafeja F, Anemona A, Basile V, Hilbert AK, De Coster I, Rondini S, Micoli F, Qasim Khan RM, Marchetti E, Di Cioccio V, Saul A, Martin LB, Podda A. Safety, immunogenicity and dose ranging of a new Vi-CRM$_{197}$ conjugate vaccine against typhoid fever: randomized clinical testing in healthy adults. PLoS One. 2011;6(9):e25398. doi: 10.1371/journal.pone.0025398.

Responsible Party:	Novartis
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