ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 05/05/2014

ClinicalTrials.gov ID: NCT00595309

Study Identification

Unique Protocol ID:	IC51-311
Brief Title:	Effect of a Booster Dose of the Japanese Encephalitis Vaccine IC51
Official Title:	Effect of a Booster Dose of the Japanese Encephalitis Vaccine IC51 on Long Term Immunogenicity. An Uncontrolled, Open-label Phase 3 Study.
Secondary IDs:	

Study Status

Record Verification:	May 2014
Overall Status:	Completed
Study Start:	December 2007
Primary Completion:	October 2009 [Actual]
Study Completion:	October 2009 [Actual]

Sponsor/Collaborators

Sponsor:	Valneva Austria GmbH
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No

Review Board:	Approval Status: Not required Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Germany: Paul-Ehrlich-Institut Austria: Agency for Health and Food Safety

Study Description

Brief Summary:	The objective is to assess the effect of a booster vaccination on immunogenicity of IC51 in terms of seroconversion rate.
Detailed Description:	

Conditions

Conditions:	Japanese Encephalitis
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Prevention
Study Phase:	Phase 3
Intervention Model:	Single Group Assignment
Number of Arms:	1
Masking:	Open Label
Allocation:	N/A
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	198 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: A	Biological/Vaccine: IC51 IC51, 6 mcg, intramuscular (i.m.) booster vaccination 15 months after the primary immunization

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: Yes

Criteria: Main Inclusion Criteria:

- Healthy adults who completed the primary immunization in study IC51 309
- Male and female healthy subjects aged at least 18 years with written informed consent and either no childbearing potential or negative pregnancy test

Main Exclusion Criteria:

• History of immunodeficiency or immunosuppressive therapy, known Human Immunodeficiency Virus (HIV), or drug addiction including alcohol dependence

Contacts/Locations

Study Officials: Susanne Eder
Study Director
Intercell AG

Locations: Austria
Medizinische Universität Wien, Universitätsklinik für Klinische Pharmakologie
Vienna, Austria

Germany
Berliner Zentrum Reise- und Tropenmedizin
Berlin, Germany

Austria
Zentrum für Reisemedizin, Dependance für klinische Studien
Vienna, Austria

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	subjects participating in preceeding study IC51-309 were contacted. First Subject In December 2007, Last Subject In March 2008; study sites: center of pharmacology and travel clinics
Pre-Assignment Details	subjects participating in study IC51-309 without major Protocol Deviations

Reporting Groups

	Description
IC51 Booster Group	IC51, 6 mcg, intramuscular (i.m.) booster vaccination 15 months after the primary immunization in study IC51-309

Overall Study

	IC51 Booster Group
Started	198
Completed	194
Not Completed	4
Lost to Follow-up	1
planned vaccination against yellow fever	1
acute infection after V0	1
personal reason	1

Baseline Characteristics

Reporting Groups

	Description
IC51 Booster Group	IC51, 6 mcg, intramuscular (i.m.) booster vaccination 15 months after the primary immunization in study IC51-309

Baseline Measures

	IC51 Booster Group
Number of Participants	198
Age, Categorical [units: participants]	
<=18 years	0
Between 18 and 65 years	197
>=65 years	1
Age, Continuous [units: years] Mean (Standard Deviation)	31.2 (9.9)
Gender, Male/Female [units: participants]	
Female	104
Male	94
Region of Enrollment [units: participants]	
Austria	103
Germany	95

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Seroconversion Rate
Measure Description	
Time Frame	at Month 12 after booster

Safety Issue?	No

Analysis Population Description

Intent-To-Treat Population which includes all subjects entered into the study who received the booster vaccination

Reporting Groups

	Description
IC51 Booster Group	IC51, 6 mcg, intramuscular (i.m.) booster vaccination 15 months after the primary immunization in study IC51-309

Measured Values

	IC51 Booster Group
Number of Participants Analyzed	198
Seroconversion Rate [units: percent] Number (95% Confidence Interval)	98.5 (95.6 to 99.5)

2. Secondary Outcome Measure:

Measure Title	Safety and Adverse Events
Measure Description	
Time Frame	up to Month 12 after booster
Safety Issue?	Yes

Outcome Measure Data Not Reported

3. Secondary Outcome Measure:

Measure Title	Seroconversion
Measure Description	
Time Frame	at D28 and Month 6 after booster
Safety Issue?	No

Outcome Measure Data Not Reported

4. Secondary Outcome Measure:

Measure Title	Geometric Mean Titer
Measure Description	
Time Frame	D28, Month 6 and Month 12 after booster
Safety Issue?	No

Outcome Measure Data Not Reported

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
IC51 Booster Group	IC51, 6 mcg, intramuscular (i.m.) booster vaccination 15 months after the primary immunization in study IC51-309

Serious Adverse Events

	IC51 Booster Group	
	Affected/At Risk (%)	# Events
Total	8/198 (4.04%)	
Blood and lymphatic system disorders		
Anaemia [A]	1/198 (0.51%)	1
Injury, poisoning and procedural complications		
Injury [B]	1/198 (0.51%)	1
Open wound [B]	1/198 (0.51%)	1
Musculoskeletal and connective tissue disorders		
Bursitis [B]	1/198 (0.51%)	1
Nervous system disorders		
Carotid Artery Stenosis [B]	1/198 (0.51%)	1

	IC51 Booster Group	
	Affected/At Risk (%)	# Events
Epilepsy [B]	1/198 (0.51%)	1
Renal and urinary disorders		
Cystitis Noninfective [B]	1/198 (0.51%)	1
Surgical and medical procedures		
Breast Cosmetic Surgery [B]	1/198 (0.51%)	1
Vascular disorders		
Thrombosis [B]	1/198 (0.51%)	1

A Term from vocabulary, MedDRA 10.1
B Term from vocabulary, MedDRA (10.1)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 1%

	IC51 Booster Group	
	Affected/At Risk (%)	# Events
Total	96/198 (48.48%)	
Blood and lymphatic system disorders		
Hypochronic Anaemia [A]	2/198 (1.01%)	
Gastrointestinal disorders		
Abdominal Pain Upper [A]	4/198 (2.02%)	
Diarrhoea [A]	4/198 (2.02%)	
Nausea [A]	6/198 (3.03%)	
General disorders		
Fatigue [A]	14/198 (7.07%)	
Influenza Like Illnes [A]	19/198 (9.6%)	
Pyrexia [A]	5/198 (2.53%)	

	IC51 Booster Group	
	Affected/At Risk (%)	# Events
Immune system disorders		
Allergy To Animal [A]	2/198 (1.01%)	
Infections and infestations		
Acute Tonsillitis [A]	2/198 (1.01%)	
Bronchitis [A]	7/198 (3.54%)	
Cystitis [A]	4/198 (2.02%)	
Gastroenteritis [A]	6/198 (3.03%)	
Influenza [A]	2/198 (1.01%)	
Nasopharyngitis [A]	30/198 (15.15%)	
Pharyngitis [A]	2/198 (1.01%)	
Rhinitis [A]	2/198 (1.01%)	
Sinusitis [A]	2/198 (1.01%)	
Urinary Tract Infection [A]	2/198 (1.01%)	
Injury, poisoning and procedural complications		
Limb Injury [A]	2/198 (1.01%)	
Investigations		
Alanine Aminotransferase Increased [A]	2/198 (1.01%)	
Musculoskeletal and connective tissue disorders		
Arthralgia [A]	3/198 (1.52%)	
Myalgia [A]	10/198 (5.05%)	
Nervous system disorders		
Headache [A]	22/198 (11.11%)	
Reproductive system and breast disorders		

	IC51 Booster Group	
	Affected/At Risk (%)	# Events
Dysmenorrhoea [A]	2/198 (1.01%)	
Respiratory, thoracic and mediastinal disorders		
Cough [A]	5/198 (2.53%)	
Vascular disorders		
Haematoma [A]	2/198 (1.01%)	
Hypertension [A]	3/198 (1.52%)	

A Term from vocabulary, MedDRA (10.1)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

There IS 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.

Results Point of Contact:

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