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

ClinicalTrials.gov ID: NCT00595465

Study Identification

Unique Protocol ID:	IC51-310
Brief Title:	Comparison of Three Commercial Batches of the Japanese Encephalitis Vaccine IC51
Official Title:	Comparison of Three Commercial Batches of the Japanese Encephalitis Vaccine IC51. Double Blind, Randomized, Controlled Phase 3 Study.
Secondary IDs:	

Study Status

Record Verification:	May 2014
Overall Status:	Completed
Study Start:	December 2007
Primary Completion:	February 2008 [Actual]
Study Completion:	June 2008 [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 demonstrate equivalence of three commercial IC51 batches in terms of geometric mean titers for anti-JEV neutralizing antibody
Detailed Description:	

Conditions

Conditions:	Japanese Encephalitis
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Prevention
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	3
Masking:	Double Blind (Subject, Investigator)
Allocation:	Randomized
Endpoint Classification:	
Enrollment:	389 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: IC51 Batch A	Biological/Vaccine: Japanese Encephalitis purified inactivated vaccine IC51 6 mcg i.m. injection on Day 0 and Day 28
Active Comparator: IC51 Batch B	Biological/Vaccine: Japanese Encephalitis purified inactivated vaccine IC51 6 mcg i.m. injection on Day 0 and Day 28
Active Comparator: IC51 Batch C	Biological/Vaccine: Japanese Encephalitis purified inactivated vaccine IC51 6 mcg i.m. injection on Day 0 and Day 28

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: Yes

Criteria: Main Inclusion Criteria:

- Male and female healthy adults 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: Nicole Haas
Study Director
Intercell AG

Locations: Austria
Medizinische Universität Wien, Universitätsklinik für Klinische Pharmakologie
Vienna, Austria, 1090

Germany
Klinik und Poliklinik für Innere Medizin der Universität Rostock
Rostock, Germany, 18057

Berliner Zentrum Reise- und Tropenmedizin
Berlin, Germany, 10117

Klinikum der Universität München, Abteilung für Infektions- und Tropenmedizin
Munich, Germany, 80802

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
IC51 Batch IC51/07E/006A	
IC51 Batch IC51/07E/007A	
IC51 Batch IC51/07E/008A	

Overall Study

	IC51 Batch IC51/07E/006A	IC51 Batch IC51/07E/007A	IC51 Batch IC51/07E/008A
Started	130	129	128
Completed	124	125	121
Not Completed	6	4	7
Adverse Event	4	3	3
Pregnancy	0	0	1

	IC51 Batch IC51/07E/006A	IC51 Batch IC51/07E/007A	IC51 Batch IC51/07E/008A
Protocol Violation	2	1	0
Lost to Follow-up	0	0	2
administrative reason	0	0	1

Baseline Characteristics

Reporting Groups

	Description
IC51 Batch IC51/07E/006A	
IC51 Batch IC51/07E/007A	
IC51 Batch IC51/07E/008A	

Baseline Measures

	IC51 Batch IC51/07E/006A	IC51 Batch IC51/07E/007A	IC51 Batch IC51/07E/008A	Total
Number of Participants	130	129	128	387
Age, Categorical [units: participants]				
<=18 years	0	0	0	0
Between 18 and 65 years	130	128	127	385
>=65 years	0	1	1	2
Age, Continuous [units: years] Mean (Standard Deviation)	29.3 (8.6)	28.9 (9.4)	30.2 (10.5)	29.5 (9.5)
Gender, Male/Female [units: participants]				
Female	71	83	74	228
Male	59	46	54	159

	IC51 Batch IC51/07E/006A	IC51 Batch IC51/07E/007A	IC51 Batch IC51/07E/008A	Total
Region of Enrollment Europe [units: participants]	130	129	128	387

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Geometric Mean Titer (GMT) for Anti-JEV Neutralizing Antibody
Measure Description	
Time Frame	Day 56
Safety Issue?	No

Analysis Population Description

Per Protocol Population (PP Population, N= 364): includes all subjects randomized who received at least one dose of study medication without any major protocol violations identified at the blind data review meeting.

Reporting Groups

	Description
IC51 Batch IC51/07E/006A	
IC51 Batch IC51/07E/007A	
IC51 Batch IC51/07E/008A	

Measured Values

	IC51 Batch IC51/07E/006A	IC51 Batch IC51/07E/007A	IC51 Batch IC51/07E/008A
Number of Participants Analyzed	124	121	119
Geometric Mean Titer (GMT) for Anti-JEV Neutralizing Antibody [units: titers] Mean (Standard Deviation)	160.8 (398.0)	188.2 (410.2)	168.4 (483.6)

2. Secondary Outcome Measure:

Measure Title	Seroconversion Rate
Measure Description	

Time Frame	Day 56
Safety Issue?	No

Outcome Measure Data Not Reported

3. Secondary Outcome Measure:

Measure Title	Safety and Adverse Events
Measure Description	
Time Frame	Day 56
Safety Issue?	Yes

Outcome Measure Data Not Reported

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	389 subjects were randomized, 2 of them were not treated

Reporting Groups

	Description
IC51 Batch IC51/07E/006A	
IC51 Batch IC51/07E/007A	
IC51 Batch IC51/07E/008A	

Serious Adverse Events

	IC51 Batch IC51/07E/006A	IC51 Batch IC51/07E/007A	IC51 Batch IC51/07E/008A
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	2/130 (1.54%)	1/129 (0.78%)	0/128 (0%)
Gastrointestinal disorders			
Abdominal Pain	0/130 (0%)	1/129 (0.78%)	0/128 (0%)
Infections and infestations			
Tubo-Ovarian Abscess	1/130 (0.77%)	0/129 (0%)	0/128 (0%)
Injury, poisoning and procedural complications			

	IC51 Batch IC51/07E/006A	IC51 Batch IC51/07E/007A	IC51 Batch IC51/07E/008A
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Humerus Fracture	1/130 (0.77%)	0/129 (0%)	0/128 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 2%

	IC51 Batch IC51/07E/006A	IC51 Batch IC51/07E/007A	IC51 Batch IC51/07E/008A
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	64/130 (49.23%)	74/129 (57.36%)	74/128 (57.81%)
Blood and lymphatic system disorders			
Lymphadenopathy	4/130 (3.08%)	1/129 (0.78%)	1/128 (0.78%)
Ear and labyrinth disorders			
Vertigo	1/130 (0.77%)	4/129 (3.1%)	1/128 (0.78%)
Gastrointestinal disorders			
Abdominal Pain	0/130 (0%)	1/129 (0.78%)	3/128 (2.34%)
Abdominal Pain Upper	0/130 (0%)	0/129 (0%)	3/128 (2.34%)
Diarrhoea	4/130 (3.08%)	4/129 (3.1%)	3/128 (2.34%)
Nausea	12/130 (9.23%)	10/129 (7.75%)	9/128 (7.03%)
Vomiting	2/130 (1.54%)	3/129 (2.33%)	4/128 (3.12%)
General disorders			
Fatigue	17/130 (13.08%)	19/129 (14.73%)	14/128 (10.94%)
Influenza Like Illness	19/130 (14.62%)	25/129 (19.38%)	25/128 (19.53%)
Injection Site Haematoma	2/130 (1.54%)	4/129 (3.1%)	2/128 (1.56%)
Injection Site Pain	4/130 (3.08%)	5/129 (3.88%)	1/128 (0.78%)
Pyrexia	8/130 (6.15%)	3/129 (2.33%)	3/128 (2.34%)
Infections and infestations			
Bronchitis	3/130 (2.31%)	4/129 (3.1%)	2/128 (1.56%)
Gastroenteritis	1/130 (0.77%)	2/129 (1.55%)	3/128 (2.34%)
Nasopharyngitis	7/130 (5.38%)	9/129 (6.98%)	7/128 (5.47%)

	IC51 Batch IC51/07E/006A	IC51 Batch IC51/07E/007A	IC51 Batch IC51/07E/008A
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Rhinitis	3/130 (2.31%)	3/129 (2.33%)	7/128 (5.47%)
Musculoskeletal and connective tissue disorders			
Myalgia	14/130 (10.77%)	10/129 (7.75%)	15/128 (11.72%)
Nervous system disorders			
Headache	23/130 (17.69%)	36/129 (27.91%)	38/128 (29.69%)
Respiratory, thoracic and mediastinal disorders			
Cough	5/130 (3.85%)	0/129 (0%)	0/128 (0%)
Pharyngolaryngeal Pain	3/130 (2.31%)	2/129 (1.55%)	6/128 (4.69%)

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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