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

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Study Identification

Unique Protocol ID:	IC51-309
Brief Title:	Comparison of Three Batches of the Japanese Encephalitis Vaccine IC51
Official Title:	Comparison of Three 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:	September 2006
Primary Completion:	April 2007 [Actual]
Study Completion:	September 2007 [Actual]

Sponsor/Collaborators

Sponsor:	Valneva Austria GmbH
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? No

	Delayed Posting?
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CBER IND/IDE Number: 8589 Serial Number: Has Expanded Access? No
Review Board:	Approval Status: Approved Board Name: PEI Board Affiliation: Phone: Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Germany: Paul-Ehrlich-Institut Austria: Agency for Health and Food Safety United States: Food and Drug Administration

Study Description

Brief Summary:	The objective is to demonstrate equivalence of three IC51 batches in terms of Geometric Mean Titers for anti-JEV neutralizing antibody.
Detailed Description:	This is a randomized, controlled, multi-center, double blind phase 3 study. The study population consists of male and female healthy subjects, aged at least 18 years. 624 subjects will be enrolled at approximately 6 sites in study centers in Austria and Germany.

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:	Safety/Efficacy Study
Enrollment:	636 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: IC51 Group A IC51 (JE-PIV) 6 mcg i.m. with 2 injections (days 0 and 28) with a vaccine produced from one out of three IC51 batches	Biological/Vaccine: IC51 6 mcg, intramuscularly [i.m.], 0.5 mL Other Names: • Japanese Encephalitis purified inactivated vaccine
Active Comparator: IC51 Group B IC51 (JE-PIV) 6 mcg i.m. with 2 injections (days 0 and 28) with a vaccine produced from one out of three IC51 batches	Biological/Vaccine: IC51 6 mcg, intramuscularly [i.m.], 0.5 mL Other Names: • Japanese Encephalitis purified inactivated vaccine
Active Comparator: IC51 Group C IC51 (JE-PIV) 6 mcg i.m. with 2 injections (days 0 and 28) with a vaccine produced from one out of three IC51 batches	Biological/Vaccine: IC51 6 mcg, intramuscularly [i.m.], 0.5 mL Other Names: • Japanese Encephalitis purified inactivated vaccine

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 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 HIV, drug addiction including alcohol dependence

Contacts/Locations

Study Officials: Susanne Eder, Mag.
Study Director
Intercell AG

Locations:

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
IC51 Group A	IC51 (JE-PIV) 6 mcg i.m. with 2 injections (days 0 and 28) with a vaccine produced from one out of three IC51 batches
IC51 Group B	IC51 (JE-PIV) 6 mcg i.m. with 2 injections (days 0 and 28) with a vaccine produced from one out of three IC51 batches
IC51 Group C	IC51 (JE-PIV) 6 mcg i.m. with 2 injections (days 0 and 28) with a vaccine produced from one out of three IC51 batches

Overall Study

	IC51 Group A	IC51 Group B	IC51 Group C
Started	214	213	212
Completed	200	210	202
Not Completed	14	3	10
Withdrawal by Subject	1	0	1
Adverse Event	4	1	2
Pregnancy	0	2	0
Protocol Violation	1	0	2
Lost to Follow-up	5	0	3
administrative	3	0	2

Baseline Characteristics

Reporting Groups

	Description
IC51 Group A	IC51 (JE-PIV) 6 mcg i.m. with 2 injections (days 0 and 28) with a vaccine produced from one out of three IC51 batches
IC51 Group B	IC51 (JE-PIV) 6 mcg i.m. with 2 injections (days 0 and 28) with a vaccine produced from one out of three IC51 batches
IC51 Group C	IC51 (JE-PIV) 6 mcg i.m. with 2 injections (days 0 and 28) with a vaccine produced from one out of three IC51 batches

Baseline Measures

	IC51 Group A	IC51 Group B	IC51 Group C	Total
Number of Participants	214	213	212	639
Age, Continuous [1] [units: years] Mean (Standard Deviation)	31.7 (10.8)	31.3 (11.0)	30.7 (10.3)	31.3 (10.7)
Gender, Male/Female [1] [units: participants]				
Female	108	123	119	350
Male	104	90	92	286

	IC51 Group A	IC51 Group B	IC51 Group C	Total
Region of Enrollment Europe [units: participants]	214	213	212	639

[1] numbers based on Safety Population: subjects with at least one vaccination

Outcome Measures

1. Primary Outcome Measure:

Measure Title	GMT for Anti-JEV Neutralizing Antibody
Measure Description	Equivalence between batches with regards to GMT was postulated if all three pair-wise 95 % Confidence Intervals for GMT ratios were between 0.5 and 2.
Time Frame	day 56
Safety Issue?	No

Analysis Population Description

Per Protocol Population (observed values)

Reporting Groups

	Description
IC51 Group A	IC51 (JE-PIV) 6 mcg i.m. with 2 injections (days 0 and 28) with a vaccine produced from one out of three IC51 batches
IC51 Group B	IC51 (JE-PIV) 6 mcg i.m. with 2 injections (days 0 and 28) with a vaccine produced from one out of three IC51 batches
IC51 Group C	IC51 (JE-PIV) 6 mcg i.m. with 2 injections (days 0 and 28) with a vaccine produced from one out of three IC51 batches

Measured Values

	IC51 Group A	IC51 Group B	IC51 Group C
Number of Participants Analyzed	197	202	200
GMT for Anti-JEV Neutralizing Antibody [units: GMT] Geometric Mean (95% Confidence Interval)	160.71 (140.54 to 183.76)	272.24 (237.22 to 312.43)	127.56 (109.51 to 148.57)

2. Secondary Outcome Measure:

Measure Title	Safety
Measure Description	Safety laboratory parameters, rate of SAEs and medically attended AEs, systemic and local tolerability
Time Frame	study duration
Safety Issue?	Yes

Outcome Measure Data Not Reported

3. Secondary Outcome Measure:

Measure Title	SCR for Anti-JEC Neutralizing Antibody Titer
Measure Description	
Time Frame	day 56
Safety Issue?	No

Outcome Measure Data Not Reported

Reported Adverse Events

Time Frame	up to Month 6
Additional Description	[Not specified]

Reporting Groups

	Description
IC51 Group A	IC51 (JE-PIV) 6 mcg i.m. with 2 injections (days 0 and 28) with a vaccine produced from one out of three IC51 batches
IC51 Group B	IC51 (JE-PIV) 6 mcg i.m. with 2 injections (days 0 and 28) with a vaccine produced from one out of three IC51 batches
IC51 Group C	IC51 (JE-PIV) 6 mcg i.m. with 2 injections (days 0 and 28) with a vaccine produced from one out of three IC51 batches

Serious Adverse Events

	IC51 Group A	IC51 Group B	IC51 Group C
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	3/212 (1.42%)	2/213 (0.94%)	5/211 (2.37%)
Gastrointestinal disorders			
Acute Abdomen	0/212 (0%)	0/213 (0%)	1/211 (0.47%)
Reflux Oesophagitis	1/212 (0.47%)	0/213 (0%)	0/211 (0%)
Hepatobiliary disorders			
Cholecystitis Acute	0/212 (0%)	0/213 (0%)	1/211 (0.47%)
Infections and infestations			
Erysipelas	0/212 (0%)	1/213 (0.47%)	0/211 (0%)
Herpes Zoster	0/212 (0%)	0/213 (0%)	1/211 (0.47%)
Peritonsillar Abscess	0/212 (0%)	1/213 (0.47%)	0/211 (0%)
Respiratory Tract Infection	1/212 (0.47%)	0/213 (0%)	0/211 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast Cancer	0/212 (0%)	0/213 (0%)	1/211 (0.47%)
Nervous system disorders			
Intracranial Aneurysm	1/212 (0.47%)	0/213 (0%)	0/211 (0%)
Renal and urinary disorders			
Renal Colic	0/212 (0%)	0/213 (0%)	1/211 (0.47%)

Other Adverse Events

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

	IC51 Group A	IC51 Group B	IC51 Group C
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	102/212 (48.11%)	124/213 (58.22%)	114/211 (54.03%)
Gastrointestinal disorders			
Diarrhoea	2/212 (0.94%)	5/213 (2.35%)	4/211 (1.9%)
Nausea	10/212 (4.72%)	21/213 (9.86%)	15/211 (7.11%)

	IC51 Group A	IC51 Group B	IC51 Group C
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
General disorders			
Fatigue	21/212 (9.91%)	30/213 (14.08%)	34/211 (16.11%)
Influenza Like Ilness	24/212 (11.32%)	35/213 (16.43%)	32/211 (15.17%)
Infections and infestations			
Acute Tonsillitis	5/212 (2.36%)	0/213 (0%)	0/211 (0%)
Gastroenteritis	1/212 (0.47%)	7/213 (3.29%)	2/211 (0.95%)
Nasopharyngitis	28/212 (13.21%)	34/213 (15.96%)	30/211 (14.22%)
Rhinitis	12/212 (5.66%)	12/213 (5.63%)	10/211 (4.74%)
Musculoskeletal and connective tissue disorders			
Back Pain	4/212 (1.89%)	5/213 (2.35%)	1/211 (0.47%)
Myalgia	14/212 (6.6%)	21/213 (9.86%)	18/211 (8.53%)
Nervous system disorders			
Headache	42/212 (19.81%)	51/213 (23.94%)	52/211 (24.64%)
Respiratory, thoracic and mediastinal disorders			
Pharyngolaryngeal Pain	5/212 (2.36%)	6/213 (2.82%)	3/211 (1.42%)
Skin and subcutaneous tissue disorders			
Rash	4/212 (1.89%)	5/213 (2.35%)	1/211 (0.47%)

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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