ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 10/19/2012

ClinicalTrials.gov ID: NCT00605085

Study Identification

Unique Protocol ID:	IC51-302
Brief Title:	Safety and Tolerability of the Japanese Encephalitis Vaccine IC51
Official Title:	Safety and Tolerability of the Japanese Encephalitis Vaccine IC51. Double Blind, Randomized, Placebo Controlled Phase 3 Study
Secondary IDs:	

Study Status

Record Verification:	October 2012
Overall Status:	Completed
Study Start:	October 2005
Primary Completion:	
Study Completion:	November 2006 [Actual]

Sponsor/Collaborators

Sponsor:	Valneva Austria GmbH
Responsible Party:	
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial?

	Delayed Posting?
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CBER IND/IDE Number: 8589 Serial Number: 0025 Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	The objective is to investigate the safety and tolerability of Japanese Encephalitis vaccine IC51 with an inactive control in healthy subjects aged > or = 18 years
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:	2
Masking:	Double Blind (Subject, Investigator)
Allocation:	Randomized

Endpoint Classification: Safety Study

Enrollment: 2675 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 IC51	Biological/Vaccine: Japanese Encephalitis purified inactivated vaccine (IC51) IC51 (JE-PIV), 6 mcg, i.m. injection, 2 vaccinations, days 0 and 28
Placebo Comparator: 2 Placebo	Biological/Vaccine: Placebo Placebo: Phosphate-buffered saline (PBS) solution containing 0.1% aluminum hydroxide as an adjuvant, 0.5 mL, i.m. injection, 2 injections, days 0 and 28

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: Yes

Criteria: Inclusion Criteria:

- At least 18 years of age
- Written informed consent obtained prior to study entry

Exclusion Criteria:

- Use of any other investigational or non-registered drug or vaccine in addition to the study vaccine during the study period or within 30 days preceding the first dose of study vaccine
- History of any previous JE vaccination (e.g. JE-VAX®)
- Immunodeficiency including post-organ-transplantation or immunosuppressive therapy
- A family history of congenital or hereditary immunodeficiency
- History of autoimmune disease
- Any acute infections within 2 weeks prior to enrollment
- Known or suspected HIV Infection
- Pregnancy, lactation or unreliable contraception in female subjects

Contacts/Locations

Study Officials: Astrid Kaltenboeck, Ph.D.
Study Director
Intercell AG

Locations:

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
IC51	IC51
Placebo	Placebo

Overall Study

	IC51	Placebo
Started	2012	663
Completed	1962	638
Not Completed	50	25
Withdrawal by Subject	8	5
Adverse Event	9	5
Pregnancy	2	0
Protocol Violation	3	2

	IC51	Placebo
Lost to Follow-up	10	5
administrative reasons	18	8

Baseline Characteristics

Reporting Groups

	Description
IC51	IC51
Placebo	Placebo

Baseline Measures

	IC51	Placebo	Total
Number of Participants	1993	657	2650
Age, Continuous [units: years] Mean (Standard Deviation)	33.9 (13.3)	33.4 (13)	33.8 (13.2)
Gender, Male/Female [units: participants]			
Female	1088	378	1466
Male	905	279	1184
Region of Enrollment [units: participants]			
Australia	294	100	394
Europe	1236	406	1642
United States	463	151	614

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Safety and Tolerability up to Day 56
Measure Description	calculation based on safety population, numbers provide percentages of participants with Adverse Events (AEs)
Time Frame	Day 56

Safety Issue?	Yes

Analysis Population Description
Safety Population

Reporting Groups

	Description
IC51	IC51
Placebo	Placebo

Measured Values

	IC51	Placebo
Number of Participants Analyzed	1993	657
Safety and Tolerability up to Day 56 [units: percentage of participants with AEs]	58.9	56.6

2. Secondary Outcome Measure:

Measure Title	Rates of Serious Adverse Events and Medically Attended Adverse Events
Measure Description	
Time Frame	until Day 56
Safety Issue?	Yes

Outcome Measure Data Not Reported

3. Secondary Outcome Measure:

Measure Title	Changes in Laboratory Parameters
Measure Description	
Time Frame	until Day 56
Safety Issue?	Yes

Outcome Measure Data Not Reported

4. Secondary Outcome Measure:

Measure Title	SCR and GMT of Subjects With Concomitant Vaccinations

Measure Description	
Time Frame	until Day 56
Safety Issue?	No

Outcome Measure Data Not Reported

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	Safet population (N = 2650): All subjects who entered the study and received at least one vaccination. All analyses based on the safety population were carried out using the actual treatment received. The safety population was used for all safety and tolerability analyses and for the analysis of demographic and background data.

Reporting Groups

	Description
IC51	IC51
Placebo	Placebo

Serious Adverse Events

	IC51	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	10/1993 (0.5%)	6/657 (0.91%)
Cardiac disorders		
Acute Coronary Syndrome	0/1993 (0%)	1/657 (0.15%)
Gastrointestinal disorders		
Proctalgia	0/1993 (0%)	1/657 (0.15%)
Rectal Haemorrhage	1/1993 (0.05%)	0/657 (0%)
General disorders		
Chest Pain	1/1993 (0.05%)	0/657 (0%)
Infections and infestations		
Abscess Limb	1/1993 (0.05%)	0/657 (0%)

	IC51	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Appendicitis	1/1993 (0.05%)	2/657 (0.3%)
Injury, poisoning and procedural complications		
Face Injury	1/1993 (0.05%)	0/657 (0%)
Facial Bones Fracture	1/1993 (0.05%)	0/657 (0%)
Ulna Fracture	1/1993 (0.05%)	0/657 (0%)
Renal and urinary disorders		
Calculus Urinary	0/1993 (0%)	1/657 (0.15%)
Reproductive system and breast disorders		
Adnexa Uteri Pain	1/1993 (0.05%)	0/657 (0%)
Ovarian Cyst Ruptured	1/1993 (0.05%)	0/657 (0%)
Ovarian Torsion	1/1993 (0.05%)	0/657 (0%)
Skin and subcutaneous tissue disorders		
Dermatomyositis	1/1993 (0.05%)	0/657 (0%)
Vascular disorders		
Curculatory Collapse	0/1993 (0%)	1/657 (0.15%)

Other Adverse Events

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

	IC51	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	917/1993 (46.01%)	292/657 (44.44%)
Gastrointestinal disorders		
Nausea	131/1993 (6.57%)	49/657 (7.46%)
General disorders		
Fatigue	227/1993 (11.39%)	77/657 (11.72%)
Influenza Like Illness	248/1993 (12.44%)	78/657 (11.87%)
Pyrexia	64/1993 (3.21%)	20/657 (3.04%)

	IC51	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Infections and infestations		
Nasopharyngitis	94/1993 (4.72%)	26/657 (3.96%)
Musculoskeletal and connective tissue disorders		
Myalgia	311/1993 (15.6%)	102/657 (15.53%)
Nervous system disorders		
Headache	559/1993 (28.05%)	173/657 (26.33%)

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:

Name/Official Title: Senior Manager Clinical Research
Organization: Intercell AG
Phone: +43 1 206 20 Ext: 1175
Email: kdubischar-kastner@intercell.com