ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 04/09/2014

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Study Identification

Unique Protocol ID:	IC51-304
Brief Title:	Rapid Immunization Study of the Japanese Encephalitis Vaccine IC51
Official Title:	Phase 3 Study to Compare a Rapid Immunization Regime With the Standard Regime of IC51 as Vaccine for Japanese Encephalitis
Secondary IDs:	

Study Status

Record Verification:	April 2014
Overall Status:	Completed
Study Start:	September 2005
Primary Completion:	February 2006 [Actual]
Study Completion:	November 2007 [Actual]

Sponsor/Collaborators

Sponsor:	Valneva Austria GmbH
Responsible Party:	Sponsor
Collaborators:	

Oversight

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

	Delayed Posting? No
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CBER IND/IDE Number: 8589 Serial Number: 0028 Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	The study investigates a rapid immunization regime of the Japanese Encephalitis vaccine IC51 (JE-PIV) in healthy subjects aged > or = 18 years
Detailed Description:	This is a multicenter, observer blinded, controlled, randomized phase 3 study. The study population consists of healthy male and female volunteers, aged at least 18 years. Approximately 375 volunteers will be enrolled at approximately 2 to 3 sites.

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:	Single Blind (Subject)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	374 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: IC51 2 x 6 mcg 2 x 6 mcg (microgram)	Biological/Vaccine: IC51 Other Names: • Japanese Encephalitis purified inactivated vaccine
Active Comparator: IC51 1 x 12 mcg 1 x 12 mcg (microgram)	Biological/Vaccine: IC51 Other Names: • Japanese Encephalitis purified inactivated vaccine
Active Comparator: IC51 1 x 6 mcg 1 x 6 mcg (microgram)	Biological/Vaccine: IC51 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:	Inclusion Criteria:

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

Exclusion Criteria:

- History of clinical manifestation of any flavivirus infection

- History of vaccination against Japanese encephalitis (JE), Yellow fever and Dengue fever (an anti-JEV neutralizing antibody titer >= 1:10 at baseline is acceptable for inclusion, these subjects will be part of the safety population, but will not be analyzed for immunogenicity in the per-protocol analysis)
- 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
- Immunodeficiency including post-organ-transplantation or immunosuppressive therapy
- A family history of congenital or hereditary immunodeficiency
- History of autoimmune disease
- Any acute infections within 4 weeks prior to enrollment
- Infection with HIV, Hepatitis B or Hepatitis C
- Pregnancy, lactation or unreliable contraception in female subjects

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 2 x 6 mcg	2 x 6 mcg (microgram)
IC51 1 x 12 mcg	1 x 12 mcg (microgram)
IC51 1 x 6 mcg	1 x 6 mcg (microgram)

Overall Study

	IC51 2 x 6 mcg	IC51 1 x 12 mcg	IC51 1 x 6 mcg
Started	125	124 [1]	125 [2]
Completed	123 [3]	123 [3]	122 [3]
Not Completed	2	1	3

[1] 124 subjects randomized to this group, 125 subjects received 1x12 mcg.(Safety Population: N=125)
[2] 125 subjects randomized to this group, 124 subjects received 1x6 mcg.(Safety Population: N=124)
[3] The Participant Flow shows all study participants randomized.Prim. Outcome is based on PP Population

Baseline Characteristics

Reporting Groups

	Description
IC51 2 x 6 mcg	2 x 6 mcg (microgram)
IC51 1 x 12 mcg	1 x 12 mcg (microgram)
IC51 1 x 6 mcg	1 x 6 mcg (microgram)

Baseline Measures

	IC51 2 x 6 mcg	IC51 1 x 12 mcg	IC51 1 x 6 mcg	Total
Number of Participants	125	125	124	374
Age, Continuous [units: years] Mean (Standard Deviation)	39.6 (14.2)	41.2 (15.0)	41.6 (14.8)	40.8 (14.7)
Gender, Male/Female [1] [units: participants]				
Female	71	65	61	197
Male	54	60	63	177
Region of Enrollment [units: participants]				
United Kingdom	58	58	57	173
Germany	67	67	67	201

[1] Baseline Characteristics are based on Safety Population: all randomized subjects who received at least one vaccination, analysed using the treatment actually received.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	SCR (Seroconversion Rate) at Day 56
Measure Description	Seroconversion rate: percentage of subjects with >= 1:10 anti-JEV neutralizing antibody titer
Time Frame	day 56
Safety Issue?	No

Analysis Population Description

The Participant Flow shows all study participants randomized. The Primary Outcome is based on the Per-Protocol-Population (all randomized subjects without major protocol deviation

Reporting Groups

	Description
IC51 1 x 12 mcg	
IC51 2x6 mcg	
IC51 1x6 mcg	

Measured Values

	IC51 1 x 12 mcg	IC51 2x6 mcg	IC51 1x6 mcg
Number of Participants Analyzed	115	115	119
SCR (Seroconversion Rate) at Day 56 [units: percentage of participants] Number (95% Confidence Interval)	41.2 (32.2 to 50.3)	97.3 (94.4 to 100.0)	25.6 (17.7 to 33.6)

Statistical Analysis 1 for SCR (Seroconversion Rate) at Day 56

Statistical Analysis Overview	Comparison Groups	IC51 1 x 12 mcg, IC51 2x6 mcg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	Yes

	Comments	Assessment of non-inferiority of IC51 1x12 mcg vs. IC51 2x6 mcg at Day 56 based on the difference (IC51 1x12 mcg - IC51 2x6 mcg) in SCRs in the PP population. Non-inferiority of IC51 1 x 12 mcg compared to IC51 2 x 6 mcg was accepted if the lower limit of the 95% CI of the adjusted for center SCR difference (IC51 1 x 12 mcg - IC51 2 x 6 mcg) was higher than the noninferiority margin at -10%.

Statistical Test of Hypothesis	P-Value	>0.99
	Comments	[Not specified]
	Method	Mantel Haenszel
	Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	SCR at Day 10, 28 and 35
Measure Description	
Time Frame	Day 10, 28 and 35
Safety Issue?	No

Outcome Measure Data Not Reported

3. Secondary Outcome Measure:

Measure Title	GMT at Day 10, 28, 35 and 56
Measure Description	
Time Frame	Day 10, 28, 35 and 56
Safety Issue?	No

Outcome Measure Data Not Reported

4. Secondary Outcome Measure:

Measure Title	Safety
Measure Description	AEs, Local and systemic tolerability, Safety laboratory parameters
Time Frame	Study duration
Safety Issue?	Yes

Outcome Measure Data Not Reported

Reported Adverse Events

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

Reporting Groups

	Description
IC51 2 x 6 mcg	2 x 6 mcg (microgram)
IC51 1 x 12 mcg	1 x 12 mcg (microgram)
IC51 1 x 6 mcg	1 x 6 mcg (microgram)

Serious Adverse Events

	IC51 2 x 6 mcg		IC51 1 x 12 mcg		IC51 1 x 6 mcg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	0/125 (0%)		1/125 (0.8%)		0/124 (0%)	
General disorders						
Chest pain	0/125 (0%)	0	1/125 (0.8%)	1	0/124 (0%)	0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	IC51 2 x 6 mcg		IC51 1 x 12 mcg		IC51 1 x 6 mcg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	78/125 (62.4%)		82/125 (65.6%)		78/124 (62.9%)	
General disorders						
Fatique	9/125 (7.2%)	12	18/125 (14.4%)	21	11/124 (8.87%)	11
Influenza like illness	21/125 (16.8%)	22	27/125 (21.6%)	31	22/124 (17.74%)	26
Musculoskeletal and connective tissue disorders						

	IC51 2 x 6 mcg		IC51 1 x 12 mcg		IC51 1 x 6 mcg	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Myalgia	25/125 (20%)	26	37/125 (29.6%)	41	36/124 (29.03%)	40
Nervous system disorders						
Headache	30/125 (24%)	40	34/125 (27.2%)	49	34/124 (27.42%)	51
Respiratory, thoracic and mediastinal disorders						
Pharyngolaryngeal pain	8/125 (6.4%)	8	6/125 (4.8%)	6	6/124 (4.84%)	6

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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