Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 11:32:07 GMT)

CTRI Number	CTRI/2010/091/000301 [Registered on: 27/04/2010] -
Last Modified On	15/03/2013
Post Graduate Thesis	
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	A first-in-man clinical trial to evaluate the safety and immunogenicity of different doses of a malaria Vaccine (JAIVAC-1) in healthy Indian Male Subjects between 18 to 45 years of age
Scientific Title of Study	A Phase I, Randomised, Controlled, Dose-Escalating, Single-Blind Clinical Trial to Evaluate the Safety and Immunogenicity of JAIVAC-1 Vaccine (PfMSP-119 and PfF2) formulated with Montanide ISA 720 in Healthy Indian Male Subjects between 18 to 45 Years of Age

Secondary IDs if Any

Secondary ID	Identifier
JAIVAC-1_1_09	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Preethi Shivyogi
Designation	
Affiliation	
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Chetan ChitnisProf Virendra Chauhan
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Affiliation	
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Source of Monetary or Material Support

Source of Monetary or Material Support
> European Vaccine Initiative UniversitätsKlinikum Heidelberg Im Neuenheimer Feld ? 307 69120 Heidelberg - Germany

Primary Sponsor

Primary Sponsor Details	
Name	International Center for Genetic Engineering and Biotechnology MVDP
Address	Aruna Asaf Ali Road, New Delhi-110067,India The Capital Court,Transcend Business Centre Olof Palme Marg, New Delhi-110067 India
Type of Sponsor	Research institution

Details of Secondary Sponsor

Name	Address
European Vaccine Initiative UniversitätsKlinikum Heidelberg Im Neuenheimer Feld ? 307 69120 Heidelberg - Germany	

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr James John	Lotus Lab Pvt. Ltd	100 feet road,3rd Block, Koramangala-560034 Bangalore KARNATAKA	91-80-22370912 91-80-22370911 james@lotuslabs.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
IEC Consultants	Approved	16/04/2010	Yes

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	03/02/2010

Health Condition / Problems Studied

Health Type	Condition
	Testing Plasmodium falciparum Malaria Vaccine

Intervention / Comparator Agent

Type	Name	Details
Intervention	JAIVAC-1 Vaccine (PfMSP-119 and PfF2) formulated with Montanide ISA 720	Deatils provided in "Brief Summary"
Comparator Agent	Hepatitis B vaccine	Details provided in "Brief Summary"

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	45.00 Year(s)
Gender	Male
Details	1. Male subject aged 18 to 45 years (both inclusive) 2. Subject with general good health based on the medical history and clinical examination 3. Subject must be willing to sign the Informed Consent Form 4. Subject must be reachable by phone during the entire study period (12 months) 5. Subject must be capable and willing to complete and return diary cards and to attend all follow-up visits 6. Male subject must agree to use

	one of the following medicallyacceptable birth control measures throughout the duration of the study (birth control counselling and measures will be provided by sites as required) ? Double barrier method (e.g. condom with spermicidal jelly) used for the entire study period Or ? Should be Surgically sterile (vasectomy)

Exclusion Criteria

Exclusion Criteria	
Details	1. Subject with evidence of IgG antibodies against PfMSP-119 and PfF2 as measured by ELISA 2. Subject with prior history of immunisation with Hepatitis B vaccine 3. Subject with known history of malaria 4. Subject with history of allergic reactions, hypersensitivity or anaphylaxis to any of the components of the study vaccines (JAIVAC-1 ? Montanide ISA 720 malaria vaccine or Hepatitis B vaccine) (including adjuvant or peptide) or with history of serious allergic reactions to any substance, requiring hospitalisation or emergency medical care 5. Subject with previous vaccination with any other malaria candidate vaccines 6. Subject with use of an investigational or non-registered drug or vaccine other than the study vaccines within three (3) months preceding the first study vaccination, or planned use during the entire clinical trial period 7. Subject, who receives any vaccination or gamma globulin during the three-month period prior to the first vaccination 8. Subject with chronic administration (defined as more than 14 days) of immuno-suppressants or other immune-modifying drugs within six months prior to the first vaccination. This includes any dose level of oral steroids or inhaled steroids, but not topical steroids 9. Subjects will be excluded if AST 40 IU/L, ALT 41 IU/L, ? GT 71 IU/L, Total Bilirubin 1.2 mg/ dL, Indirect Bilirubin 1.2 mg/ dL, Direct Bilirubin 0.4 mg/dL, Serum Creatinine 1.2 mg/ dL(Appendix B and B-1). 10. Subjects will be excluded in case of out of range values for the following parameters: Hemoglobin 13 to 18 g/ dL, RBC count 4.0 to 7.0 × 10E6/µL TLC 4.0 to 11.0 × 10E3/µL, platelet count 150 to 500 × 10E3/µL, Neutrophils 40 to 75 % or Eosinophils 10 %, Sodium 136 to 145 mEq/L, Potassium 3.5 to 5.1 mEq/L, Random Blood Glucose 45 to 130 mg/dl and Alkaline Phosphatase 40 to 129 U/L (Appendix B and B-1) 11. Subjects with other clinically significant abnormal laboratory values based on the normal reference range (Refer Appendix B and B1) apart from the laboratory parameters listed above.

Method of Generating Random Sequence	Permuted block randomization, fixed
Method of Concealment	Pre-numbered or coded identical Containers
Blinding/Masking	Participant Blinded

Primary Outcome

Outcome	Timepoints
The safety profile will be assessed on the basis of the following criteria &#56256;&#56451; Immediate reactogenicity (any event occurring within the first three (3) hours after each vaccination, with emphasis on allergic reactions) &#56256;&#56451; Local and systemic reactogenicity (any event occurring from three (3) hours post vaccination on Day 0 till Day 14	NA

	after each dose) &#56256;&#56451; Any unsolicited adverse events 28 days after each vaccination &#56256;&#56451; Any Serious Adverse Event (SAE) occurring from the first dose of vaccine till the last follow-up visit. &#56256;&#56451; Biological safety, 28 days after each vaccination, in reference with the baseline before the first dose, by measuring the following parameters: ? Haematology: RBC Count, Haemoglobin*, Haematocrit/Packed Cell Volume (PCV), MCV (Mean Corpuscular Volume), MCH (Mean Corpuscular Haemoglobin), MCHC (Mean Corpuscular Haemoglobin Concentration) on Days -14, 28, 56, 180, 208, 365 ? Platelet Count and Total Leukocyte Count (TLC) along with Differential Leukocyte Count (DLC) on Days -14, 28, 56, 180, 208, 365. *If the haemoglobin drops below 13 gm/dL, then a direct Coomb?s test and a peripheral blood smear/film will be prepared and examined for evidence of possible haemolysis ? Serum Chemistry: Potassium, Sodium, AST, ALT, Direct, Indirect and Total Bilirubin, Alkaline Phosphatase, Gamma Glutamyl Transpeptidase (γGT), Creatinine, and Random blood glucose on Days -14, 28, 56, 180, 208, 365 The Investigator will be responsible for causality assessment i.e. assessment of the relationship of the AE to either of the assigned the study vaccines, using the following definitions: related or not related.	

Secondary Outcome

Outcome	Timepoints
? The humoral response to the candidate vaccine antigen will be assessed (quantitative assessment) by measuring the level of IgG antibodies developed against PfMSP-119 and PfF2 by ELISA on Days 0, 28, 56, 180, 208 and 365 ? The humoral response to the candidate vaccine antigen will be assessed (qualitative assessment) to verify the ability of the IgG antibodies developed against PfMSP-119 and PfF2 to recognise the native proteins, namely, PfMSP1 and EBA175 in late stage P. falciparum schizonts and merozoites by IFA on Days 0, 28, 56, 180, 208 and 365.	NA

Target Sample Size	**Total Sample Size=**45 **Sample Size from India=**45 **Final Enrollment numbers achieved (Total)=** **Final Enrollment numbers achieved (India)=**
Phase of Trial	Phase 1
Date of First Enrollment (India)	09/08/2010
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**2 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable

Recruitment Status of Trial (India)	Completed
Publication Details	
Brief Summary	This Phase I, first in man study is designed as a randomized, controlled, single-blind and dose-escalating clinical study for the assessment of the safety and immunogenicity of JAIVAC-1 malaria vaccine (PfMSP-119 and PfF2) formulated with Montanide ISA 720 as an adjuvant in healthy Indian male subjects between 18 to 45 years of age. The study involves testing of three (3) different dosages of JAIVAC-1 malaria vaccine in three different dosage cohorts. Hepatitis B vaccine will serve as an active control. Each Cohort will have 15 subjects. The randomization schedule will be 2:1, i.e. 10 subjects will receive the investigational vaccine and 5 subjects will be administered hepatitis- B, the control vaccine. Thus, in total in this study, 30 subjects will receive JAIVAC-1―Montanide ISA720 (10 subjects at each dosage cohort) and 15 subjects will receive control vaccine. Both the study vaccines will be administered via intramuscular route and shall have a 3-dose schedule on Days 0, 28 and 180. In the first Cohort subjects will receive 0.1 ml of investigational vaccine. If found to be safe and well tolerated second cohort will receive 0.25 ml of investigational vaccine and finally Cohort 3 will receive 0.5 ml of investigational vaccine. Each cohort will be staggered into sub-cohorts such that the subjects in each cohort will be enrolled over a three-day period. The first three (3) subjects of the first dose (Cohort 1) will be kept under observation for 24 hrs following vaccination. The decision of the 24-hour housing for the remaining subjects will be jointly taken by the Principal Investigator and Medical and Safety Monitor, DLS.