Clinical Trial Details (PDF Generation Date :- Thu, 22 Oct 2020 20:56:59 GMT)

CTRI Number	CTRI/2014/04/004538 [Registered on: 11/04/2014] - **Trial Registered Retrospectively**
Last Modified On	10/03/2014
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Randomized Factorial Trial
Public Title of Study	Rabies G Protein Vaccine study for immunization against Rabies
Scientific Title of Study	Safety and Immunogenicity Study of Rabies G Protein Vaccine Administered as a Simulated Post-exposure Immunization in Healthy Volunteers

Secondary IDs if Any

Secondary ID	Identifier
CRSC12002 Ver 4.0 dated 02/09/13	Protocol Number

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

Details of Principal Investigator	
Name	Dr Deepak Sawhney
Designation	Head BA/BE & CR
Affiliation	CRO-Cadila Pharmaceuticals Ltd
Address	1389, Trasad Road, Dholka, India 1389, Trasad Road, Dholka, India Ahmadabad GUJARAT 387810 India
Phone	02714-221481
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Details Contact Person (Scientific Query)

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Name	Dr Deepak Sawhney
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Cadila Pharmaceuticals Ltd.

Primary Sponsor

Primary Sponsor Details	
Name	Cadila Pharmaceuticals Limited
Address	Corporate Campus, Sarkhej-Dholka Highway, Village: Bhat, Ahmedabad – 382210, Gujarat, India
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Moti Talpada	Apollo Hospitals International Limited	Dept. of infectious disease & internal medicine, Bhat, GIDC Estate, Gandhinagar – 382 428, Gujarat, India. Gandhinagar GUJARAT	079-66701800 079-66701843 mdtalpada2001@yahoo .com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee Apollo hospitals international limited	Approved	28/11/2013	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	09/10/2013

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Rabies

Intervention / Comparator Agent

Type	Name	Details
Comparator Agent	Rabies vaccine (Rabipur)	Intramuscular injection will be given on the Day 0,3,7,14,28
Intervention	Rabies G Protein Vaccine (5mcg)	0.5 ml Intramuscular Vaccine will be given of 5mcg of Rabies G Protein vaccine on day schedules 0,3
Intervention	Rabies G Protein Vaccine (5mcg)	0.5 ml Intramuscular Vaccine will be given of 5mcg of Rabies G Protein vaccine on day schedules 0,3,7
Intervention	Rabies G Protein Vaccine (5mcg)	0.5 ml Intramuscular Vaccine will be given of 5mcg of Rabies G Protein vaccine on day schedules 0,7
Intervention	Rabies G Protein Vaccine (5mcg	0.5 ml Intramuscular Vaccine will be given of 5mcg of Rabies G Protein vaccine on day schedules 0,7,10
Intervention	Rabies G Protein Vaccine (10mcg)	0.5 ml Intramuscular Vaccine will be given of 10mcg of Rabies G Protein vaccine on day schedules 0,3

Intervention	Rabies G Protein Vaccine (10mcg)	0.5 ml Intramuscular Vaccine will be given of 10mcg of Rabies G Protein vaccine on day schedules 0,3,7
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Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	- Healthy human volunteers of 18 to 65 years - During the first stage-I of the study, only male volunteers will be recruited. - Volunteers with seronegative status for anti-rabies antibodies at baseline - Volunteers who are in good health at the time of entry into the study as determined by medical history, physical examination and clinical judgment of the investigator

	- Volunteers willing to comply with the requirements of protocol (volunteer for simulated post-exposure immunization and, willing to be available for all study visits as well blood drawing) - Volunteer who has signed or Institutional Review Board (IRB) approved informed consent form (ICF) - Volunteer available by phone - Documented negative test for human immuno virus (HIV-1/2), HBsAg or HCV - Negative urine pregnancy test for female volunteer of child-bearing potential - Female volunteer of child bearing potential or sexually active male volunteer with partners of childbearing potential must practice acceptable barrier contraception (e.g., condoms, intrauterine contraceptive devices, or sterilization) during treatment and at least 2 months after the last dose of vaccine.

Exclusion Criteria

Exclusion Criteria	
Details	- History of potential rabies exposure or who has received rabies vaccination(active/passive) -?History of known hypersensitivity/allergy to egg proteins, animal cell product, insect proteins or NP9 (The VLP vaccine to be used in this study does not contain egg proteins, but comparators in randomized trials may) or any excipients of vaccine formulation - Who has received any other vaccines within 6 months prior to enrollment - Body temperature ?38.0°C (? 100.4° F) prior to first vaccination - Volunteer with any acute infectious disease at the time of enrollment - Volunteer with any chronic illness - Administration of immunomodulating agents within six months prior to administration of study medications - Volunteers on concomitant antimalarials or treatment with an anti-malarial drug, up to two months prior to the study - History or currently consuming drugs of abuse or alcohol - Volunteer with deficiency of IgG, IgM & IgA - Volunteer with an abnormal clinical chemistry, hematology or urinalysis results that is considered clinically significant by the investigator or the sponsor. Pregnant or lactating female volunteer, or planning to become pregnant during the projected duration of the clinical trial, or who cannot provide a credible history of reliable contraceptive practices - Participation in another clinical trial in the past 3 months

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Pre-numbered or coded identical Containers
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints

- Proportion of volunteers with solicited adverse events, unsolicited adverse events and serious adverse events? - Proportion of volunteers with seroprotection levels - Geometric mean titers of anti-rabies antibodies	0-42 days

Secondary Outcome

Outcome	Timepoints
Safety & Immunogenicity	0-180 days

Target Sample Size	**Total Sample Size=**170 **Sample Size from India=**170 **Final Enrollment numbers achieved (Total)=** **Final Enrollment numbers achieved (India)=**
Phase of Trial	Phase 1/ Phase 2
Date of First Enrollment (India)	22/01/2014
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**8 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	
Brief Summary	Cadila Pharmaceuticals Limited, India has successfully tested VLP-based Rabies G Protein Vaccine in preclinical models and to take the development further, it needs to be tested in humans. Present study is the FIH trial involving Rabies G Protein Vaccine to evaluate its safety and immunogenicity. When new rabies vaccines are introduced, their immunogenicity is evaluated by comparing the RABV neutralizing antibody titres induced by the vaccine being tested with those induced by a vaccine of demonstrated efficacy. As rabies is a fatal disease, randomized controlled human trials involving untreated comparison groups could not be carried out for ethical reasons.8 Lesser doses (2 or 3) of post-exposure prophylaxis might see savings to healthcare system and individuals in terms vaccine cost and additional medical visits, in addition to overall better treatment compliance. Based on our preclinical experience and above statements, we postulate that Rabies G Protein Vaccine will provide faster and similar seroprotection against rabies in comparison to worldwide approved Rabipur vaccine as a simulated post-exposure immunization in healthy volunteers.