Clinical Trial Details (PDF Generation Date :- Sun, 28 Nov 2021 00:37:18 GMT)

CTRI Number	CTRI/2016/08/007137 [Registered on: 02/08/2016] - **Trial Registered Prospectively**
Last Modified On	07/10/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	Immunogenicity and safety study of Rabies G protein Vaccine administered as a simulated post-exposure immunization in healthy volunteers
Scientific Title of Study	Immunogenicity and safety study of Rabies G protein Vaccine administered as a simulated post-exposure immunization in healthy volunteers

Secondary IDs if Any

Secondary ID	Identifier
CRSC15001 Version 3 Dated 12 March 2016	Protocol Number

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

Details of Principal Investigator	
Name	Dr Maharshi Desai
Designation	Principal Investigator
Affiliation	Apollo Hospital International Limited
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Designation	Manager
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Address	Cadila Pharmaceuticals Limited 1389, Trasad Road, Dholka Ahmadabad GUJARAT 387810 India
Phone	9825603307
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Cadila Pharmaceuticals Limited

Primary Sponsor

Primary Sponsor Details	
Name	Cadila Pharmaceuticals Limited
Address	1389, Trasad Road, Dholka, Ahmedabad – 387810, 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 V Ramasubramanian	Apollo Hospitals	Apollo Hospitals, No. 21, Greams Lane, Off Greams Road, Chennai- 600006 Chennai TAMIL NADU	04428295045 idisdoc@gmail.com
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Dr Ravish H S	Kempegowda Institute of Medical Science	Kempegowda Institute of Medical Science, Athibabbe road, Near BDA Complex, Banashankari 2nd Stage, Bengaluru, Karnataka 560070 Bangalore KARNATAKA	919900562743 drravishhs@rediffmail.com
Dr Samir Malhotra	Postgraduate Institute Of Medical Education And Research (PGIMER)	Postgraduate Institute Of Medical Education And Research (PGIMER), Sector 12,Chandigarh 160012 Chandigarh CHANDIGARH	919417016343 smal.pgi@gmail.com
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Dr Prakash Kurmi	Shivam Hospital	Shivam Hospital, C-4, Satyanarayan Society, Jashodanagar cross road, Maninagar, Ahmedabad-380008,Gujarat Ahmadabad GUJARAT	919925047695 Dr_prakashkurmi@yahoo.co.in
Dr Durga Madhab Satapathy	Veer Surendra Sai Institute of Medical Sciences & research	Ayurvihar, Burla, Sambalpur. Pin - 768017 Sambalpur ORISSA	919861084185 drdurgams@rediffmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee, S.P Medical College & A.G Hospitals, PBM Hospital, Bikaner	Approved	28/07/2016	No
Institutional Ethics Committee, Apollo Hospitals International Ltd, Gandhinagar, Gujarat	Approved	12/05/2016	No
Institutional Ethics Committee, Grant government medical college & JJ group of hospital, Byculla, Mumbai	Approved	18/10/2016	No
Institutional Ethics Committee, Post Graduate Institute of Medical Education Research, Chandigarh	Approved	03/08/2016	No
Institutional Ethics Committee- Apollo Hospitals, Chennai	Approved	19/06/2016	No
Institutional Research & Ethics Committee, Veer Surendra Sai Institute of Medical Sciences & Research, Sambalpur, Odisha	Approved	22/11/2016	No
KIMS Institutional Ethics Committee, Kemegowda Institute of Medical Sciences, Bangalore	Approved	15/09/2016	No
Samvedna Hospital	Approved	12/02/2017	No

Ethics Committee, B 27/88 G, Ravindrapuri, Varanasi-221005			
Sanjivani Hospital Ethics Committee 1, New Uday Park Soc., Nr. Sunrise Park, Vastrapur, Ahmedabad	Approved	24/06/2016	No
Shivam ethics committee, Institution Ethics Committee	Approved	04/07/2016	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	09/05/2016

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Healthy

Intervention / Comparator Agent

Type	Name	Details
Intervention	Rabies G protein Vaccine (Dose: 50 ?g/0.5 ml) Intramuscular Injection once on Day 0, 3 and 7.	Manufactured by Cadila Pharmaceuticals Limited, India
Comparator Agent	Rabipur Vaccine (Dose: 2.5 IU/ml, One dose Intramuscularly on Day 0, 3, 7, 14 & 28 (5 dose)	Manufactured by Novartis Healthcare Private Limited, India

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. • Volunteers with seronegative status for Rabies Virus Neutralizing Antibody (RVNA) titers at screening (by ELISA method) • 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 (willing to be available for all study visits as well blood drawing). • Volunteer who has signed Institutional Review Board (IRB) approved informed consent form (ICF) • Documented negative test for human immunodeficiency 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 receipt of 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. • Receipt of any other vaccines within 1 month 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 anti-malarials or treatment with an anti-malarial drug, up to two months prior to the study. • History or current use of drugs of abuse or alcohol. • Volunteer with deficiency of IgG, IgM & IgA. • Volunteer with abnormal clinical chemistry, hematology or urinalysis results that are 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	Pharmacy-controlled Randomization
Blinding/Masking	Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
Subjects with seroprotection at 14 days post 1st dose of study vaccine	14 days

Secondary Outcome

Outcome	Timepoints
Safety by monitoring subjects with adverse events Time frame 0 to 180 days Subjects with seroprotection at day 42 post 1st dose of study vaccine An exploratory analysis will be done to compare seroprotection rate at day 90 and 180	42,90 and 180 days

Target Sample Size	**Total Sample Size=**800 **Sample Size from India=**800 **Final Enrollment numbers achieved (Total)=**800 **Final Enrollment numbers achieved (India)=**800
Phase of Trial	Phase 3
Date of First Enrollment (India)	17/08/2016
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**2 **Months=**4 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	
Brief Summary	This study is a randomized, Open labeled assessor blind, Phase-III, parallel design comparative clinical trial. Objective of study is to assess safety and immunogenicity of Rabies G protein Vaccine (investigational vaccine) 10 µg at Day 0, 3 versus marketed Rabipur vaccine (comparator vaccine) 2.5 IU/ml, at Days 0, 3, 7, 14 & 28 to be administered as a simulated post-exposure (PEP) immunization. The sero-negative volunteers at screening (by ELISA method) will be randomized in a ratio of 2:1 to receive either test or comparator vaccine, respectively. Vaccination will be done in the deltoid muscle.On vaccination day, volunteers will remain at the hospital for a period of at least 6 hours for observation and assessment of

local injection site reactions and the occurrence of any adverse events (AEs).

The primary outcome measures will be Subjects with seroprotection at 14 days post 1st dose of study vaccine & the secondary outcomes will be Subjects with seroprotection at day 42 post 1st dose of study vaccine and Safety by monitoring subjects with adverse events [Time frame: 0-180 days]

Window period of ±2 days will be allowed for day 14 and day 42. An exploratory analysis will be done to compare seroprotection rate at day 90 & 180. Rabies Virus Neutralizing Antibody (RVNA) titers will be analyzed by rapid fluorescent focus inhibition test (RFFIT) for Immunogenicity results.

Final Clinical Study Report will include data of safety & immunogenicity up to day 180 & will be submitted to DCGI for market authorization. Volunteer will be considered to have completed the study if they are

followed through 180 days ±7 days after first vaccination. Additionally on day 365±14 post first vaccination, one additional blood sample will be obtained for immunogenicity analysis. Separate supplementary report will be prepared for safety & immunogenicity data up to day 365.