"A randomized controlled trial to study the immunogenecity and safety of Curvic® in vaccinated population for COVID-19"

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Sponsor

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INTRODUCTION:

Vaccination is protective against COVID 19 infections. Based on recent studies by Shreepad Shree Vallabh SSV Phytopharmaceuticals, it has been scientifically that Curvic® is effective against all species of coronavirus by blocking the Main Protein (M_{pro}). The efficacy of Curvic® have been proven in quarantined patients as an immunity booster and also in a randomized double blind trial for the management of SARS-COV-2 (COVID-19) infection. We plan to conduct the current study to evaluate the role of Curvic® in vaccinated population for COVID 19.

OBJECTIVE:

Primary objective

To access the immunogenicity of Curvic® given to vaccinated population for COVID-19 in comparison to only vaccinated population for COVID-19.

Secondary objective

To compare the safety of Curvic® given to vaccinated population for COVID-19 in comparison to only vaccinated population for COVID-19.

STUDY POPULATION:

This study population includes 50 vaccinated healthy volunteers for COVID-19 divided in two groups.

Group A: Curvic® given to vaccinated population for COVID-19 for 120 days

Group B: Only vaccinated population for COVID-19

DESIGN AND DURATION OF THE STUDY:

Prospective observational study

Study duration 120 days

METHODOLOGY:

The study shall include 50 healthy volunteers eligible for vaccination for COVID-19. These volunteers will be screened for Absolute Lymphocyte Count (CD3+, CD4+ and

CD8+) and Anti SARS-CoV-2 spike protein (S1 /S2) IgG. Once vaccinated, they will be divided in two groups:

Group A: (N=25) Curvic® given to vaccinated population for COVID-19 for 120 days

Group B: (N=25) Only vaccinated population for COVID-19

Once vaccinated they will follow the protocol for post vaccination. Based on the type of vaccination, whichever is the due date for 2nd vaccination will be followed by the respective volunteer. After completion of 120 days from first dose of vaccination, the volunteers will be again screened for Absolute Lymphocyte Count (CD3+, CD4+ and CD8+) and Anti SARS-CoV-2 spike protein (S1 /S2) IgG in both the groups.

INCLUSION CRITERIA:

1. Adult male or female human volunteer of age 18-65 years (inclusive of both)
2. Eligible for vaccination for COVID-19
3. Willing and able to provide written, signed and dated informed consent
4. If you had no medical history or evidence of COVID-2019
5. If you had no acute infections and/or respiratory diseases within 14 days before enrollment.
6. If you had no evidence of vaccine-induced reactions or complications after receiving immunobiological products in the past medical history.
7. If you are willing to give consent to use effective contraception methods during the study
8. If you have negative urine pregnancy test at the screening visit (for child-bearing aged women)
9. If you have negative human immunodeficiency virus (HIV 1 & 2), syphilis, hepatitis B and C test results

EXCLUSION CRITERIA:

1. Aged < 18 years and >65 of ages are excluded from the study
2. Any vaccination/immunization within 30 days before the enrollment
3. Any treatment with steroids (except hormonal contraceptives) and/or immunoglobulins or other blood products within 30 days before the enrollment

4. Any treatment with immunosuppressive therapy within 3 months before the enrollment
5. any drug allergy (anaphylactic shock, Quincke's edema, polymorphic exudative eczema, atopy, serum disease), hypersensitivity or allergic reaction to immunobiological products, known allergic reactions to study drug components, acute exacerbation of allergic diseases on enrollment day
6. Any neoplasms in the past medical history
7. Donated blood or plasma within 3 months before the enrollment
8. Any history or evidence of splenectomy
9. Any immunodeficiency state
10. Any history or evidence of anorexia or protein deficiency of any origin
11. Alcohol or drug addiction in the past medical history
12. Participation in any other interventional clinical trial within 3 months
13. Any other condition that the study physician considers as a barrier to the trial completion as per the protocol
14. Pregnancy or breast-feeding
15. Subjects who are tested positive for Corona virus disease through RT-PCR SARS CoV-2 Test and positive anti COVID antibodies within 3 months before the enrollment

SUBJECT RECRUITMENT:

Healthy volunteers will be recruited into the study based on the inclusion criteria and the data shall be collected i.e. Demographics, comorbidities, date of vaccination will be entered in excel. They will be closely followed up upto 120 days from first dose of vaccination for COVID-19 to observe for any adverse reactions.

RANDOMIZATION:

Computer Generated randomization

DISCONTINUATION CRITERIA:

People who got infected during study period and lost to follow up are excluded in the study.

OUTCOME MEASURES:

A. Primary:

To assess the immunogenicity of vaccines with or without Curvic® at baseline and 120 days.

B. Secondary:

To assess safety of Curvic® with or without vaccine.