ISRCTN26285740 https://doi.org/10.1186/ISRCTN26285740

# Trial to study the effect of Curvic® in vaccinated population for COVID-19

**Submission date**
14/03/2022

**Recruitment status**
No longer recruiting

**Registration date**
19/04/2022

**Overall study status**
Completed

**Last Edited**
20/04/2022

**Condition category**
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

## Plain English summary of protocol

Background and study aims
Vaccination is protective against COVID-19 infections. Based on recent studies by Shreepad Shree Vallabh SSV Phytopharmaceuticals, it has been scientifically proven that Curvic® is effective against all species of coronavirus by blocking the Main Protein (Mpro). The efficacy of Curvic® has 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 the COVID-19 vaccinated population.

Who can participate?
Adult male or female volunteers of age 18-65 years (inclusive), who are eligible for vaccination for COVID-19

What does the study involve?
After vaccination, participants will be randomly allocated to receive Curvic® or not. Blood samples will be taken at baseline and 120 days

What are the possible benefits and risks of participating?
The supplement Curvic® may benefit participants who are vaccinated for COVID-19. Curvic®, being a nutraceutical supplement, possesses no risk to the participants consuming it. This has been proven in various clinical trials carried out previously for the formulation.

Where is the study run from?
Sukhkarta Hospital (India)

When is the study starting and how long is it expected to run for?
March 2021 to February 2022

Who is funding the study?
Shreepad Shree Vallabh SSV Phytopharmaceuticals (India)

Who is the main contact?
Dr Yogesh Dound, yogesh_dound@yahoo.com

# Contact information

### Type(s)
Scientific

### Contact name
Dr Yogesh Dound

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
SSV-SF-01/2021

# Study information

### Scientific Title
A randomized controlled trial to study the immunogenicity and safety of Curvic® in a vaccinated population for COVID-19

### Acronym
SSV-SF-01/2021

### Study objectives

Vaccination is protective against COVID 19 infections. Based on recent studies by Shreepad Shree Vallabh SSV Phytopharmaceuticals, it has been scientifically proven that Curvic® is effective against all species of coronavirus by blocking the Main Protein (Mpro). The efficacy of Curvic® has 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 the vaccinated population for COVID 19.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 21/03/2021, Navsanjeevani Hospital Ethics Committee (Nashik, Maharashtra, India; +91 9822574157; navsanjeevaniec@gmail.com), ref: none provided

## Study design
Interventional randomized controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
See additional files

## Health condition(s) or problem(s) studied
Vaccinated for COVID-19

## Interventions
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.

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 to 120 days from the first dose of vaccination for COVID-19 to observe for any adverse reactions.

RANDOMIZATION:
Computer generated randomization

DISCONTINUATION CRITERIA:
People who become infected during the study period and lost to follow up are excluded.

### Intervention Type
Supplement

### Primary outcome measure
Measured by blood test at baseline and 120 days:
1. Absolute lymphocyte count (CD3+, CD4+ and CD8+)
2. Anti-SARS-CoV-2 spike protein (S1 /S2) IgG

### Secondary outcome measures
Safety of Curvic® with or without vaccine assessed through clinical biochemistry and by symptomatology at baseline and 120 days

### Overall study start date
21/03/2021

### Completion date
28/02/2022

## Eligibility

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

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
65 Years

### Sex
Both

### Target number of participants
50

### Total final enrolment
50

### Key exclusion criteria
1. Aged <18 years and >65 years
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 Coronavirus disease through RT-PCR SARS CoV-2 Test and positive anti-COVID antibodies within 3 months before the enrollment

### Date of first enrolment
01/04/2021

### Date of final enrolment
25/12/2021

## Locations

### Countries of recruitment
India

### Study participating centre
**Sukhkarta Hospital**
1st floor, Bhagchand Complex

Above Abhishek Agro
Dindori Naka
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422008

# Sponsor information

### Organisation
Shreepad Shree Vallabh SSV Phytopharmaceuticals

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### Sponsor type
Industry

### Website
http://www.ssvphytopharma.com

# Funder(s)

### Funder type
Industry

### Funder Name
Shreepad Shree Vallabh SSV Phytopharmaceuticals

# Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

## Intention to publish date
05/03/2022

## Individual participant data (IPD) sharing plan
Raw data can be shared upon request by contacting yogesh_dound@yahoo.com

## IPD sharing plan summary
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | English version 1 | 09/03/2021 | 16/03/2022 | No | Yes |
| Participant information sheet | Marathi version 1 | 09/03/2021 | 16/03/2022 | No | Yes |
| Protocol file | version 1 | 09/03/2021 | 16/03/2022 | No | No |