

# Mixing of the COVID-19 vaccines Covishield and Covaxin for safety assessment

<b>Submission date</b> 30/12/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 06/01/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/12/2022	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Vaccination is protective against COVID-19 infection. Based on recent studies by ICMR study which included 18 patients and Com- COV study, Combi Vacs trial, It has been observed that combination vaccines elicit a better immune response. There are a few studies from India on combination vaccines. We aim to assess the safety of mixing vaccines in a large number of healthy volunteers.

### Who can participate?

Healthy volunteers aged 18-65 years (inclusive of both) with no medical history or evidence of COVID-19 and not vaccinated for COVID-19/influenza

### What does the study involve?

Participants will be divided into four groups. Two groups will be given homologous vaccines and two groups will be given heterologous vaccines (mix and match). Blood samples will be collected at 28 days after the 1st dose and 14 days after the 2nd dose for assessing antibody levels.. Participants will be closely monitored for any adverse effects for 3 months.

### What are the possible benefits and risks of participating?

No adverse effects are reported from a combination of vaccines. The participants will have the benefit of a reduced risk of getting severe COVID-19.

### Where is the study run from?

Asian Healthcare Foundation (India)

### When is the study starting and how long is it expected to run for?

August 2021 to November 2021

### Who is funding the study?

Asian Healthcare Foundation (India)

Who is the main contact?  
Dr Bhanu Prakash Reddy Attunuru  
drbhanu.prakash@aighospitals.com

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Bhanu Prakash Reddy Attunuru

### Contact details

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## Additional identifiers

### Protocol serial number

COVID-19-21;Version 1.0 ;dt :11 th August ,2021

## Study information

### Scientific Title

Studying the immunogenicity and safety of combination vaccines for COVID-19

### Acronym

MIX-VAC

### Study objectives

Mixing of the vaccines Covishield and Covaxin will elicit a better immune response.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 25/08/2021, Institutional Ethics Committee, Asian Institute of Gastroenterology (IEC-ALG) (6-3-661, Somajiguda, Hyderabad - 500 082, India; +91 (0)40 23378888; iecaig2044@gmail.com), ref: AIG/IEC-CT 51/08.2021-01

### Study design

Interventional randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Prevention

## Health condition(s) or problem(s) studied

COVID-19 (SARS-CoV-2 infection)

## Interventions

200 healthy volunteers will be recruited according to the inclusion and exclusion criteria as mentioned below. After taking informed consent they will be divided into four groups by computer-generated randomisation. Two groups will be given homologous vaccines and two groups will be given heterologous vaccines (mix and match). Blood samples will be collected 28 days after the 1st dose and 14 days after the 2nd dose. Participants will be closely monitored for any adverse effects for 3 months. Blood samples will be used for assessing S1, S2, and RBD specific antibody titres.

Group 1 received Covishield on day 0 and Covishield on day 28

Group 2 received Covaxin on day 0 and Covaxin on day 28

Group 3 received Covishield on day 0 and Covaxin on day 28

Group 4 received Covaxin on day 0 and Covishield on day 28

## Intervention Type

Biological/Vaccine

## Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

Covishield, Covaxin

## Primary outcome(s)

Immunogenicity: neutralising antibody titres against S1/S2 and RBD measured by electrochemiluminescence at baseline, 28 days and 45 days after complete vaccination

## Key secondary outcome(s)

The safety of different vaccine combinations assessed on day 28 (4 weeks after 1st dose), day 45 (2weeks after 2nd dose) and day 60 using patient records, blood tests, and questionnaire:

1. Major adverse events
2. Laboratory parameters complete blood analysis, renal function tests, and liver function tests.
3. Clinical monitoring through a simple questionnaire

## Completion date

12/11/2021

## Eligibility

### **Key inclusion criteria**

1. Adult male or female human volunteer aged 18-65 years (inclusive of both) and not vaccinated for COVID-19/influenza, willing and able to provide written, signed and dated informed consent
2. Negative immunoglobulin M (IgM) SARS-CoV-2 antibodies through enzyme immunoassay test result
3. Negative COVID-2019 Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) test result at the screening visit
4. No medical history or evidence of COVID-19
5. No acute infections and/or respiratory diseases within 14 days before enrollment
6. 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. Negative urine pregnancy test at the screening visit (for childbearing aged women)
9. Negative human immunodeficiency virus (HIV 1 & 2), syphilis, hepatitis B and C test results

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

65 years

### **Sex**

All

### **Total final enrolment**

44

### **Key exclusion criteria**

1. Aged <18 years of age
2. Any vaccination/immunization within 30 days before enrollment
3. Any treatment with steroids (except hormonal contraceptives) and/or immunoglobulins or other blood products within 30 days before enrollment
4. Any treatment with immunosuppressive therapy within 3 months before 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 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 breastfeeding
15. Subjects who test positive for Coronavirus disease through RT-PCR SARS CoV-2 Test and positive anti-COVID antibodies

**Date of first enrolment**

28/08/2021

**Date of final enrolment**

20/09/2021

## **Locations**

**Countries of recruitment**

India

**Study participating centre**

**AIG Hospitals**

No 136, Plot No 2/3/4/5 Survey

1, Mindspace Rd

Gachibowli

Hyderabad

India

500032

## **Sponsor information**

**Organisation**

Asian Healthcare Foundation

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Asian Healthcare Foundation

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Bhanu Prakash Reddy Attunuru (drbhanu.prakash@aighospitals.com).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		21/03/2022	20/12/2022	Yes	No
<a href="#">Protocol file</a>	version 1.0	11/08/2021	31/12/2021	No	No