



Clinical Trial Details (PDF Generation Date :- Sun, 27 Nov 2022 11:39:03 GMT)

CTRI Number	CTRI/2021/01/030782 [Registered on: 27/01/2021] - Trial Registered Prospectively		
Last Modified On	24/06/2021		
Post Graduate Thesis	No		
Type of Trial	Observational		
Type of Study	Cohort Study		
Study Design	Other		
Public Title of Study	COVID-19 Vaccine effectiveness and hesitancy study in Healthcare Workers of Max Group of Hospitals		
Scientific Title of Study	"A prospective, longitudinal, observational, postlicensure vaccine evaluation study to assess the effectiveness of COVID-19 vaccine among the Healthcare workers of Max group of hospitals"		
Secondary IDs if Any	Secondary ID	Identifier	
	NIL	NIL	
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator		
	Name	Sujeet Jha	
	Designation	Principal Director	
	Affiliation	Max Healthcare	
	Address	Institute of Endocrinology, Diabetes, and Metabolism, Max Super Speciality Hospital, 2, Press Enclave Road, Saket South DELHI 110017 India	
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	Fax		
	Email	sujeet.jha@maxhealthcare.com	
	Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
		Name	Sujeet Jha
Designation		Principal Director	
Affiliation		Max Healthcare	
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	Email	sujeet.jha@maxhealthcare.com		
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Max Healthcare and CSIR-IGIB			
Primary Sponsor	Primary Sponsor Details			
	Name	CSIRInstitute of Genomics and Integrative Biology		
	Address	DTC Bus Depot, South Campus, Mathura Road, near to Sukhdev Vihar, New Delhi, Delhi 110025		
	Type of Sponsor	Other [Council of Scientific and Industrial Research (CSIR)]		
Details of Secondary Sponsor	Name	Address		
	Max Healthcare A Unit of Devki Devi Foundation	2, Press Enclave Road, Saket, New Delhi-110017		
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Sujeet Jha	Max Super Speciality Hospitals	Saket, Vaishali, Patparganj, Gurgaon, Shalimar Bagh, Lajpat Nagar New Delhi DELHI	9910609000 sujeet.jha@maxhealthcare.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Institutional Ethics Committee, Devki Devi Foundation	Approved	22/01/2021	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Healthy Human Volunteers		Undergoing COVID-19 vaccination	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Not applicable	Not applicable	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		
	Age To	90.00 Year(s)		
	Gender	Both		
	Details	• HCWs of Max group of hospitals, irrespective of age and gender • HCWs who are being offered Govt. of India approved COVID-19 vaccines Covishield or COVAXIN		
Exclusion Criteria	Exclusion Criteria			
	Details	Refusal to give informed consent, or contraindication to venipuncture.		
Method of Generating Random Sequence	Not Applicable			
Method of Concealment	Not Applicable			
Blinding/Masking	Not Applicable			



Primary Outcome	Outcome	Timepoints
	Seropositivity in participants after vaccination	7, 14, 28, 45, 90 days after vaccination, may be extended further
Secondary Outcome	Outcome	Timepoints
	Effectiveness of COVID-19 vaccines	30 days, 90 days, may be extended further
Target Sample Size	Total Sample Size=1000 Sample Size from India=1000 Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials	
Phase of Trial	N/A	
Date of First Enrollment (India)	05/02/2021	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=0 Months=6 Days=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Closed to Recruitment of Participants	
Publication Details	Yes, we will publish the results	
Brief Summary	<p>We have designed this study to evaluate COVID-19 vaccine effectiveness by antibody testing and evaluate vaccine hesitancy rate, among the healthcare workers of Max Group of Hospitals.</p> <p>We would do antibody testing at day 0 (vaccination day or pre-vaccination) followed by 7, 14, 28, 45, 90th day of vaccination. This study would involve a brief questionnaire asking about the health status of the participants related to COVID-19 and side-effects post-vaccination.</p>	