Clinical Trial Details (PDF Generation Date :- Wed, 28 Jul 2021 09:41:02 GMT)

CTRI Number	CTRI/2020/07/026820 [Registered on: 27/07/2020] - **Trial Registered Prospectively**
Last Modified On	26/07/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug Ayurveda
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Curcumin for COVID-19 Pre Exposure Prophylaxis
Scientific Title of Study	Curcumin for COVID-19 Pre Exposure Prophylaxis: A Randomised Controlled Trail

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	Rohit Walia
Designation	Assistant Professor Incharge Electrophysiology , Heart Failure Special Clinic
Affiliation	All India Institute of Medical Science Rishikesh
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Rohit Walia
Designation	Assistant Professor Incharge Electrophysiology , Heart Failure Special Clinic
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Source of Monetary or Material Support

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> All India Institute of Medical Science Rishikesh , Virbhadra Road , Barrage , Dehradun , Uttarakhand , India . Pin 249203

Primary Sponsor

Primary Sponsor Details	
Name	Rohit Walia
Address	Room number 25103 , Department of Cardiology , All India Institute of Medical Science Rishikesh
Type of Sponsor	Other [Principal investigator]

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
Rohit Walia	All India Institute of Medical Science Rishikesh	Room number , Department of Cardiology , All India Institute of Medical Science Rishikesh Dehradun UTTARANCHAL	8800492549 rwalia7731@yahoo.in

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
All India Institute of Medical Science Rishikesh	Approved	18/07/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	people at risk of COVID infection - health care workers , diabetes , cardiac patients

Intervention / Comparator Agent

Type	Name	Details
Comparator Agent	Placebo	Placebo Capsule oral twice daily morning evening for 12 weeks
Intervention	Curcumin	Oral Curcumin capsule 500 mg twice daily (morning , evening) for 12 weeks

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	70.00 Year(s)
Gender	Both
Details	People at risk of SARS-CoV 2 infection (healthcare professionals , attendants of COVID patients , non COVID patients admitted in hospitals or his risk groups like elderly , cardiovascular patients ,

	diabetes , obesity) Not having a previous COVID19 diagnosis Not having experienced COVID19 symptoms since 30 th Jan 2020. Not having taken any pre-exposure prophylaxis (HCQ , any other medication or Ayurvedic preparation or food supplement) Having a negative SARS-CoV 2 test before randomisation

Exclusion Criteria

Exclusion Criteria	
Details	Any chronic infection Renal failure (CrCl Known history of hypersensitivity to the study drug or any of its components Immune suppressant drugs Recent vaccination within 2 month Pregnancy Primary Immunodeficiency states • Anemia Leukopenia Thrombocytopenia Co morbidities precluding survival required for duration of study follow up

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Participant and Investigator Blinded

Primary Outcome

Outcome	Timepoints
1. SARS-CoV 2 infection rate Using RTPCR	12 weeks

Secondary Outcome

Outcome	Timepoints
Frequency of respiratory tract infections during course of study using the Wisconsin Upper Respiratory Symptom Survey	12 weeks
Number of participants with treatment-related adverse events as assessed by CTCAE v5.0.	12 weeks

Target Sample Size	**Total Sample Size=**200 **Sample Size from India=**200 **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	Phase 4
Date of First Enrollment (India)	09/08/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	no
Brief Summary	Curcumin has been proven to have anti viral , anti bacterial and anti inflammatory properties and immunomodulator. We plan to a randomised controlled trail to study curcumin as pre exposure prophylaxis in healthcare workers and high risk groups and look for Covid infection rates over a period of 12 weeks and look for COVID positivity rates over a period of 12 weeks between cur cumin vs. placebo.