



Clinical Trial Details (PDF Generation Date :- Wed, 24 Feb 2021 16:35:27 GMT)

CTRI Number	CTRI/2020/06/025613 [Registered on: 04/06/2020] - Trial Registered Prospectively	
Last Modified On	04/06/2020	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Drug	
Study Design	Randomized, Parallel Group, Placebo Controlled Trial	
Public Title of Study	Melatonin Immune Boost COVID 19 Study	
Scientific Title of Study	Melatonin For COVID 19 pre exposure prophylaxis in High Risk population . (MELATONIN IMMUNE BOOST COVID 19 STUDY)	
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
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Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> All India Institute of Medical Science Rishikesh , Virbhadr Road , Pashulok , Rishikesh , Uttarakhand			
Primary Sponsor	Primary Sponsor Details			
Name	Rohit Walia			
Address	Room number 25103 , Department of Cardiology , All India Institute of Medical Science Rishikesh ,Uttarakhand , India			
Type of Sponsor	Other [self]			
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 25103, Department of Cardiology ,All India Institute of Medical Science Virbhadr Road , Pashulok , 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	30/05/2020	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Healthy Human Volunteers		High risk for Covid 19	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Melatonin	Oral melatonin 3 mg at 6 pm daily once x 8 weeks	
	Comparator Agent	Placebo	Placebo for 8 weeks	
Inclusion Criteria	Inclusion Criteria			
	Age From	20.00 Year(s)		
	Age To	90.00 Year(s)		
	Gender	Both		
	Details	High groups for COVID 19 related disease Elderly : age > 60 years Diabetes Obesity Heart Failure Immuno suppressed patients 		
Exclusion Criteria	Exclusion Criteria			
	Details	Chronic Renal Failure		



	Chronic Hepatic Failure Any hospitalisation for past 3 months Any recent vaccination Nutrition supplements Any addiction Chronic infections live Human immunodeficiency disorder , Hepatitis B,C., etc Any autoimmune disease Irregular sleep pattern Primary immunodeficiency states Vitamin deficiency states								
Method of Generating Random Sequence	Computer generated randomization								
Method of Concealment	Centralized								
Blinding/Masking	Participant and Investigator Blinded								
Primary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>SARS-CoV 2 infection rate : Number of confirmed (positive CRP) symptomatic infections in each treatment group</td> <td>8 weeks</td> </tr> </tbody> </table>	Outcome	Timepoints	SARS-CoV 2 infection rate : Number of confirmed (positive CRP) symptomatic infections in each treatment group	8 weeks				
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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)	15/06/2020								
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	Nil								
Brief Summary	Elderly , cardiovascular , obesity are high risk for COVID related severe disease and high mortality and needs to be protected. With advance age immune system go immune senescence and innate immunity is weakened.Decrease in Melatonin has been linked to immunosenescence. Melatonin is safe, inexpensive , proven effect as adjuvant treatment for bacterial and viral infections , anti oxidative and anti inflammatory effect . Melatonin enhances the production of progenitor cells of granulocyte , macrophage and natural killer cells , increases production of IL2,IL6,IL12 and increases helper T cells. It can reverse immunosenescence of old age and immunocompromised								



states and prevent them from COVID related disease. We study Melatonin oral 3 mg vs placebo in high risk groups for prevention of COVID 19 disease. We study Covid infection rate and other infections and immune response at baseline and 8 weeks in both groups.