



# NIMS UNIVERSITY RAJASTHAN, JAIPUR

Fully empowered & incorporated as a regular & full-fledged University under  
NIMS UNIVERSITY ACT, 2008 duly recognized by Government of India  
under the provisions of the Sections 2(f) and 22 of the UGC Act, 1956.

**FACULTIES:** • Medicine • Dentistry • Engineering • Advanced Engg. • Management • Law • Pharmacy • Nursing • Science & Technology  
• Physiotherapy • Allied Health Sciences • Fashion • Media • Mass Comm. • Hospitality • Aviation • Education • Library Sciences  
• Physical Education • Films & Television etc. • *multi-specialty 1130-bedded tertiary level Hospital on campus*

## INSTITUTIONAL ETHICS COMMITTEE NIMS UNIVERSITY RAJASTHAN, JAIPUR (INDIA)

Ref. No.: NIMSUR/IEC/2020/036

Date: 04<sup>th</sup> May, 2020

To:

Name: **Prof. (Dr.) Ganpat Devpura**

Department of **Medicine**

**Sub: IEC (Institutional Ethics Committee) Approval for research project**

Institutional Ethics Committee had reviewed and discussed the research project titled "**Impact of Indian traditional Ayurvedic treatment regime for nCoV-2 (COVID-19).**" After review and discussion, members decided to accord ethical clearance and allowed the study to be undertaken at National Institute of Medical Sciences and Research, Jaipur (NIMS University Rajasthan, Jaipur).

This approval is valid till the completion of the study, please inform us in case of any serious event observed during the conduct of the study.

From:

**Member Secretary**

**Institutional Ethics Committee,**

**NIMS University Rajasthan, Jaipur**

**FULL DETAILS (Read-only) -> [Click Here to Create PDF for Current Dataset of Trial](#)**

<b>CTRI Number</b>	<b>CTRI/2020/05/025273</b> [Registered on: 20/05/2020] <b>Trial Registered Prospectively</b>	
<b>Last Modified On:</b>	20/05/2020	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Ayurveda	
<b>Study Design</b>	Randomized, Parallel Group, Placebo Controlled Trial	
<b>Public Title of Study</b>	Impact of effect of Ayurvedic treatment on novel Corona virus disease	
<b>Scientific Title of Study</b>	Impact of Indian traditional Ayurvedic treatment regime for nCoV-2 (COVID-19)	
<b>Trial Acronym</b>		
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>
	NIL	NIL
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Name</b>	Dr Ganpat Devpura
	<b>Designation</b>	Professor Medicine
	<b>Affiliation</b>	National Institute of Medical Sciences
	<b>Address</b>	Professor Department of Medicine National Institute of Medical Sciences and Research, Jaipur India 303121 NH 11 C Jaipur Delhi Highway Nims University Campus Jaipur Rajasthan India Jaipur RAJASTHAN 303121 India
	<b>Phone</b>	9829069669
	<b>Fax</b>	
	<b>Email</b>	gdevpura@yahoo.co.in
<b>Details of Contact Person Scientific Query</b>	<b>Name</b>	Dr Abhishek Sharma
	<b>Designation</b>	Assistant Professor Medicine
	<b>Affiliation</b>	National Institute of Medical Sciences
	<b>Address</b>	Professor Department of Medicine National Institute of Medical Sciences and Research, Jaipur India 303121 NH 11 C Jaipur Delhi Highway Nims University Campus Jaipur Rajasthan India Jaipur RAJASTHAN 302021 India
	<b>Phone</b>	9828816135
	<b>Fax</b>	
	<b>Email</b>	dr.abhisheksharma1987@gmail.com
<b>Details of Contact Person Public Query</b>	<b>Name</b>	Dr Abhishek Sharma
	<b>Designation</b>	Assistant Professor Medicine

	<table border="1"> <tr> <td><b>Affiliation</b></td> <td>National Institute of Medical Sciences</td> </tr> <tr> <td><b>Address</b></td> <td>Professor Department of Medicine National Institute of Medical Sciences and Research, Jaipur India 303121 NH 11 C Jaipur Delhi Highway Nims University Campus Jaipur Rajasthan India Jaipur RAJASTHAN 302021 India</td> </tr> <tr> <td><b>Phone</b></td> <td>9828816135</td> </tr> <tr> <td><b>Fax</b></td> <td></td> </tr> <tr> <td><b>Email</b></td> <td>dr.abhisheksharma1987@gmail.com</td> </tr> </table>	<b>Affiliation</b>	National Institute of Medical Sciences	<b>Address</b>	Professor Department of Medicine National Institute of Medical Sciences and Research, Jaipur India 303121 NH 11 C Jaipur Delhi Highway Nims University Campus Jaipur Rajasthan India Jaipur RAJASTHAN 302021 India	<b>Phone</b>	9828816135	<b>Fax</b>		<b>Email</b>	dr.abhisheksharma1987@gmail.com		
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<b>Fax</b>													
<b>Email</b>	dr.abhisheksharma1987@gmail.com												
<b>Source of Monetary or Material Support</b>	Patanjali Research Institute Governed by Patanjali Reserach Foundation Trust, Haridwar, Uttrakhand												
<b>Primary Sponsor</b>	<table border="1"> <tr> <td><b>Name</b></td> <td>Patanjali Research Institute</td> </tr> <tr> <td><b>Address</b></td> <td>Patanjali Research Institute Patanjali Yogpeeth Trust Haridwar, Uttarakhand</td> </tr> <tr> <td><b>Type of Sponsor</b></td> <td>Research institution</td> </tr> </table>	<b>Name</b>	Patanjali Research Institute	<b>Address</b>	Patanjali Research Institute Patanjali Yogpeeth Trust Haridwar, Uttarakhand	<b>Type of Sponsor</b>	Research institution						
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National Institute of Medical Sciences Jaipur	NH 11 C Jaipur Delhi Highway, Nims University Campus, Jaipur, Rajasthan, India												
<b>Countries of Recruitment</b>	India												
<b>Sites of Study</b>	<table border="1"> <tr> <td colspan="4" style="text-align: center;">No of Sites = 1</td> </tr> <tr> <td><b>Name of Principal Investigator</b></td> <td><b>Name of Site</b></td> <td><b>Site Address</b></td> <td><b>Phone/Fax/Email</b></td> </tr> <tr> <td>Deepak Nathiya</td> <td>National Institute of Medical Sciences</td> <td>Department of Medicine, National Institute of Medical Sciences &amp; Research, Nims University Rajasthan, Jaipur NH 11 C Jaipur Delhi Highway Nims University Campus, Jaipur, Rajasthan, India Jaipur RAJASTHAN</td> <td>9929600137  deepaknathiya@gmail.com</td> </tr> </table>	No of Sites = 1				<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>	Deepak Nathiya	National Institute of Medical Sciences	Department of Medicine, National Institute of Medical Sciences & Research, Nims University Rajasthan, Jaipur NH 11 C Jaipur Delhi Highway Nims University Campus, Jaipur, Rajasthan, India Jaipur RAJASTHAN	9929600137  deepaknathiya@gmail.com
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<b>Details of Ethics Committee</b>	<table border="1"> <tr> <td colspan="2" style="text-align: center;">No of Ethics Committees= 1</td> </tr> <tr> <td><b>Name of Committee</b></td> <td><b>Approval Status</b></td> </tr> <tr> <td>Institutional Ethics Committee</td> <td>Approved</td> </tr> </table>	No of Ethics Committees= 1		<b>Name of Committee</b>	<b>Approval Status</b>	Institutional Ethics Committee	Approved						
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<b>Health Condition / Problems Studied</b>	<b>Health Type</b>	<b>Condition</b>	
	Patients	J969  Respiratory failure, unspecified,	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>
	Intervention	Ayurvedic Therapy	Tablet Pure Ashwagandha 500mg BD, Oral, After Breakfast / Dinner Tablet Pure Giloy Extract 1000 mg BD, Oral, after Breakfast / Dinner Tablet Pure Tulsi Extract 500 mg BD, Oral, after Breakfast/Dinner Anu Taila 4 drops BD, Nasal Drop Powder Swasari Ras 2 gm BD, Oral, Before Breakfast / Dinner
	Comparator Agent	Placebo Therapy	Placebo of same dosage form by Oral / Nasal route
<b>Inclusion Criteria</b>	<b>Age From</b>	15.00 Year(s)	
	<b>Age To</b>	80.00 Year(s)	
	<b>Gender</b>	Both	
	<b>Details</b>	Asymptomatic patients Mildly symptomatic patients Moderately symptomatic patients Age 15-80 years of age Patients able to give Informed consent and follow instructions Agree to follow at 14 days and 30 days after testing positive for COVID-19	
<b>ExclusionCriteria</b>	<b>Details</b>	Severely symptomatic patients (SaO2 <90%) Acute Respiratory Distress Syndrome (ARDS) Life expectancy less than 1 year due to other co-morbid conditions	
<b>Method of Generating Random Sequence</b>	Computer generated randomization		
<b>Method of Concealment</b>			
<b>Blinding/Masking</b>			
<b>Primary Outcome</b>	<b>Outcome</b>	<b>TimePoints</b>	
	Virological Clearance as measured by RT PCR of nasopharyngeal swab	Baseline, 3 Days, 7 Days, 14 Days	
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>TimePoints</b>	
	Conversion from Symptomatic to Asymptomatic patient	Baseline, 3 Days, 7 Days, 14 Days	
	Reduction in C-reactive protein, ESR & IL-6		
	Improvement in heamatological parameters eg Total Leucocyte count		
Safety analysis			
<b>Target Sample</b>	<b>Total Sample Size="120"</b>		

<b>Size</b>	<b>Sample Size from India="120"</b> <b>Final Enrollment numbers achieved (Total)=</b> "Applicable only for Completed/Terminated trials" <b>Final Enrollment numbers achieved (India)="</b> Applicable only for Completed/Terminated trials"
<b>Phase of Trial</b>	N/A
<b>Date of First Enrollment (India)</b>	29/05/2020
<b>Date of Study Completion (India)</b>	Applicable only for Completed/Terminated trials
<b>Date of First Enrollment (Global)</b>	Date Missing
<b>Date of Study Completion (Global)</b>	Applicable only for Completed/Terminated trials
<b>Estimated Duration of Trial</b>	<b>Years="0"</b> <b>Months="2"</b> <b>Days="0"</b>
<b>Recruitment Status of Trial (Global)</b>	Not Applicable
<b>Recruitment Status of Trial (India)</b>	Open to Recruitment
<b>Publication Details</b>	NIL
<b>Brief Summary</b>	<p>COVID-19 infection is known to affect individuals with weak immunity more severely. Therefore, enhancing immunity is definitely one of the ways the doctors across the globe have been using for treating COVID-19 cases.</p> <p>The study is Interventional Randomized parallel group placebo controlled, Single Centric trial in which Impact of Indian traditional Ayurvedic treatment regime for nCoV-2 (COVID-19) will be accessed.</p> <p>To combat COVID-19 virus with Ayurveda, we have screened close to 1000 phytochemicals from more than 100 medicinal plants, in-silico. We looked for their binding affinities to COVID-19 essential proteins and host protein interactions. We have discovered that natural phytochemicals in Ashwagandha, Giloy and Tulsi indeed have potentials to combat COVID-19 and its pathogenicity.</p> <p><b>The patients who will be included in the study's active control group will receive -</b></p> <p>Tablet Swasari Ras : (500 mg)</p> <p>Tablet Pure Ashwagandha Extract : (500 mg)</p> <p>Tablet Pure Giloy Extract : (500 mg)</p> <p>Tablet Pure Tulsi Extract : (500 mg)</p> <p>Anu Taila (Nasal drop)</p> <p>The above mentioned ayurvedic medicines will be used at following dosage :</p> <p><b>In the morning:</b></p>

At-least 60 mins before break-fast : 4 drops of Anu Taila (Nasal drop), in each nostril.

At-least 30 mins before break-fast : Swasari Ras 2 gm (with luke-warm water)

At-least 30 mins after break-fast : 2 Tablets Pure Giloy Extract  
1 Tablet Pure Ashwagandha  
1 Tablet Pure Tulsi Extract (with luke-warm water)

**In the evening:**

At-least 30 mins before dinner : Swasari Ras 2 gm (with luke-warm water)

At-least 30 mins after dinner : 2 Tablets Pure Giloy Extract  
: 1 Tablet Pure Ashwagandha  
1 Tablet Pure Tulsi Extract (with luke-warm water)

The above mentioned active control group will be compared with Placebo group receiving placebo of same dosage form. Symptomatic treatment will follow in both group along with treatment.

The primary outcome of the study will be assessed by measuring virological clearance as measured by RT PCR for nasopharageal swab at baseline, 3<sup>rd</sup>day, 7<sup>th</sup>days and 14<sup>th</sup> day.

The secondary outcomes will be assessed by measuring conversion from symptomatic to asymptomatic patient, reduction in CRP protein, ESR & IL-6. Further improvement in hematological parameter, Total leucocyte count and lymphocyte count. Safety analysis will also be done.

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