



पतंजलि रिसर्च फाउण्डेशन ट्रस्ट

Patanjali Research Foundation Trust

क्रमांक
S.No. : PRFT/DA/0620/035

दिनांक
Dated : 23rd June 2020

To,
Drug Policy Section,
Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)
Government of India, NBCC Office Block-3 (2nd Floor),
East Kidwai Nagar, New Delhi - 110023

7.00 PM

Subject: Reply - News items related to "Swashri Vati" & "Cononil" for COVID 19 being publicized by Patanjali Yogapeetha, Haridwar – Regarding

Reference: Your email letter – Reference number F. No. T.11012/1/2020-DCC(AYUSH) dated: 23rd June, 2020.

Dear Sir,

At the outset, Patanjali Research Institute (PRI), Haridwar would like to convey its sincere gratitude of Ministry of AYUSH for their valuable support always for the upliftment of Ayurveda in India. This is in above mentioned reference to your letter and embedded queries on our recently conducted successful clinical trial on Ayurvedic medicines.

Please find herewith point wise reply for your kind perusal –

S. No.	Query	Reply by PRI, Haridwar
1.	Name and composition of the medicines being claimed for COVID treatment	<p>1. Tablet Pure Ashwagandha 500mg BD, Oral, After Breakfast / Dinner</p> <p>2. Tablet Pure Giloy Extract 1000 mg BD, Oral, after Breakfast / Dinner</p> <p>3. Tablet Pure Tulsi Extract 500 mg BD, Oral, after Breakfast/Dinner</p> <p>4. Anu Taila 4 drops BD, Nasal Drop</p> <p>5. Swasari Ras /Vati 2 gm BD, Oral, Before Breakfast / Dinner</p> <p>(Detail composition of Medicines being claimed are herewith for your perusal –</p> <p>a. https://www.sciencedirect.com/science/article/pii/S0753332220302547</p> <p>b. https://www.authorea.com/users/312350/articles/442940-tinospora-cordifolia-giloy-may-curb-covid-19-contagion-tinocordiside-disrupts-the-electrostatic-interactions-between-ace2-and-rbd</p>





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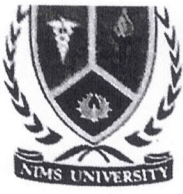
		c. https://www.sciencedirect.com/science/article/pii/S0753332220302547
	Site(s)/hospital(s), where the research study was conducted for COVID-19	<ul style="list-style-type: none"> Department of Medicine, National Institute of Medical Sciences & Research, Nims University Rajasthan, Jaipur NH 11 C Jaipur, Delhi Highway, Jaipur, Rajasthan, India
1.	IEC clearance and CTRI Registration	Both are Attached for your kind perusal. (Annexure 1 & 2)
2.	Protocol, sample size and results data of the study (ies)	<p>Protocol, Sample size are available with CTRI approval (CTRI/2020/05/025273 [Registered on: 20/05/2020] which is attached for your kind perusal. (Annexure 2)</p> <p>The brief of results is herewith for your perusal –</p> <ol style="list-style-type: none"> There were 69 % of recovery at Day 3 PCR, in Treatment group and 100 % recovery at day 7, Which is 35 % better recovery than placebo group. Serum CRP levels are lesser in treatment group than placebo group (Day 1 versus Day 7 : p<0.033) Remarkable decrease in IL-6 level among study patients. <p>Results will be uploaded on CTRI website soon.</p>
3.	Early submission of the above details is solicited	Reply being submitted on 23.06.2020, 7:00 PM IST

Sir, Please be noted that the trial was being conducted and registered with Clinical Trial Registry of India (CTRI) with ref no. CTRI/2020/05/025273, registered on 20.05.2020 (**Annexure 2**) as per the Guidelines laid down in The Gazette of India : Extraordinary, published on 21st April 2020 F. No. L.11011/8/2020 & General Guidelines for Clinical Evaluation of Ayurvedic Interventions by Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH, Government of India and was communicated to DIRECTOR GENERAL, Central Council for Research in Ayurvedic Sciences Ministry of AYUSH (Government of India) via email on dg-ccras@nic.in on 4th June 2020 by Principal Investigator Dr. G. Devpura, MD by email (Attached for your kind perusal – **Annexure 3**).

Please do not hesitate to ask, should you need more information.

Acharya Balkrishna





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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.

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• 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)

Annex 1

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

Date: 04th May, 2020

Page 1/1

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:

Mridula

Member Secretary
Institutional Ethics Committee,
NIMS University Rajasthan, Jaipur

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

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

Annet (2)
Page 1/6

Affiliation	National Institute of Medical Sciences
Address	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
Phone	9828816135
Fax	
Email	dr.abhisheksharma1987@gmail.com

2/6

Source of Monetary or Material Support

Patanjali Research Institute Governed by Patanjali Reserach Foundation Trust, Haridwar, Uttrakhand
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Primary Sponsor

Name	Patanjali Research Institute
Address	Patanjali Research Institute Patanjali Yogpeeth Trust Haridwar, Uttarakhand
Type of Sponsor	Research institution

Details of Secondary Sponsor

Name	Address
National Institute of Medical Sciences Jaipur	NH 11 C Jaipur Delhi Highway, Nims University Campus, Jaipur, Rajasthan, India

Countries of Recruitment

India

Sites of Study

No of Sites = 1			
Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
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

Details of Ethics Committee

No of Ethics Committees= 1	
Name of Committee	Approval Status
Institutional Ethics Committee	Approved

Regulatory Clearance Status from DCGI

Status	Not Applicable
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Health Condition / Problems Studied	Health Type Patients	Condition J969 Respiratory failure, unspecified,									
Intervention / Comparator Agent	<table border="1"> <thead> <tr> <th>Type</th> <th>Name</th> <th>Details</th> </tr> </thead> <tbody> <tr> <td>Intervention</td> <td>Ayurvedic Therapy</td> <td>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</td> </tr> <tr> <td>Comparator Agent</td> <td>Placebo Therapy</td> <td>Placebo of same dosage form by Oral / Nasal route</td> </tr> </tbody> </table>	Type	Name	Details	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	<p style="text-align: right; color: purple; font-size: 2em;">3/6</p>
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ExclusionCriteria	Details	Severely symptomatic patients (SaO2 <90%) Acute Respiratory Distress Syndrome (ARDS) Life expectancy less than 1 year due to other co-morbid conditions									
Method of Generating Random Sequence	Computer generated randomization										
Method of Concealment											
Blinding/Masking											
Primary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>TimePoints</th> </tr> </thead> <tbody> <tr> <td>Virological Clearance as measured by RT PCR of nasopharyngeal swab</td> <td>Baseline, 3 Days, 7 Days, 14 Days</td> </tr> </tbody> </table>	Outcome	TimePoints	Virological Clearance as measured by RT PCR of nasopharyngeal swab	Baseline, 3 Days, 7 Days, 14 Days						
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Improvement in heamatological parameters eg Total Leucocyte count											
Safety analysis											
Target Sample	Total Sample Size="120"										

4/6

Size	Sample Size from India="120" 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)	29/05/2020
Date of Study Completion (India)	Applicable only for Completed/Terminated trials
Date of First Enrollment (Global)	Date Missing
Date of Study Completion (Global)	Applicable only for Completed/Terminated trials
Estimated Duration of Trial	Years="0" Months="2" Days="0"
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	NIL
Brief Summary	<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>The patients who will be included in the study's active control group will receive -</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>In the morning:</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)

5/6

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, 3rd day, 7th days and 14th 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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DEPARTMENT OF MEDICINE

Ref. No.: NU/NCC/2020/116

Dated: June 02, 2020

To,
DIRECTOR GENERAL
Central Council for Research in Ayurvedic Sciences

Ministry of AYUSH (Government of India)
Jawahar Lai Nehru Bhartiya Chikitsa Evam Homeopathy Anusandhan Bhawan,
No. 61-65, Institutional Area, Opp. "D" Block, Janakpuri, New Delhi-110058
Tele.: 91-11-28524457, Fax: 91-11-28520748
Email: dg-ccras@nic.in

Sir / Madam,

A Clinical trial entitled "Impact of Indian Traditional Ayurvedic treatment regime for nCOV-2 (COVID-19)" registered with Clinical Trial Registry of India (CTRI) with ref no. CTRI/2020/05/025273, registered on 20.05.2020 as per the Guidelines laid down in The Gazette of India : Extraordinary, published on 21st April 2020 F. No. L.11011/8/2020 & General Guidelines for Clinical Evaluation of Ayurvedic Interventions by Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH, Government of India, is being carried out at NIMS University Rajasthan, Jaipur.

This is for your information and necessary guidance, Please

Thank you

Dr. Ganpat Devpura
Professor - Medicine &
Principal Investigator

Campus Address: NH 11 C, Jaipur-Delhi Highway, Jaipur-303121 (Rajasthan), India

Email: gdevpura@yahoo.co.in

Website: www.nimsuniversity.org



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DEPARTMENT OF MEDICINE

Ref. No.: NU/NCC/2020/115

Dated: June 02, 2020

Sh. Rohit Kumar Singh, IAS

Additional Chief Secretary
Medical, Health and Family Welfare Department,
Government of Rajasthan, Jaipur, India

Sir,

A Clinical trial entitled "Impact of Indian Traditional Ayurvedic treatment regime for nCOV-2 (COVID-19)" registered with Clinical Trial Registry of India (CTRI) with ref no. CTRI/2020/05/025273, registered on 20.05.2020 as per the Guidelines laid down in The Gazette of India : Extraordinary, published on 21st April 2020 F. No. L.11011/8/2020 & General Guidelines for Clinical Evaluation of Ayurvedic Interventions by Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH, Government of India, is being carried out at NIMS University Rajasthan, Jaipur.

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Thank you

Dr. Ganpat Devpura
Professor - Medicine &
Principal Investigator

Campus Address: NH 11 C, Jaipur-Delhi Highway, Jaipur-303121 (Rajasthan), India

Email: gdevpura@yahoo.co.in

Website: www.nimsuniversity.org



Deepak Nathiya <dnathiya@nimsuniversity.org>

Information regarding Clinical Trial

2/2

Deepak Nathiya <dnathiya@nimsuniversity.org>

To: dg-ccras@nic.in

Thu, Jun 4, 2020 at 5:40 PM

Cc: gdevpura@yahoo.co.in, Dr Balvir Singh Tomar <chancellornims@gmail.com>

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