



Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 10:15:56 GMT)

CTRI Number	CTRI/2020/05/025335 [Registered on: 24/05/2020] - Trial Registered Prospectively	
Last Modified On	19/10/2020	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Ayurveda	
Study Design	Single Arm Study	
Public Title of Study	Efficacy of AYUSH-64 (a polyherbal formulation) in COVID - 19 Cases	
Scientific Title of Study	A Pilot Study To Assess The Efficacy Of AYUSH - 64 In COVID - 19 Cases	
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	Dr N R Singh
	Designation	Professor and HOD- Kayachikitsa, Additional Director Academics
	Affiliation	Chaudhary Bahm Prakash Ayurved Charak Sansthan, New Delhi
	Address	CBPACS, Khera Dabar, Najafgarh New Delhi 110073 Additional Director office, room no G-31, CBPACS, Khera Dabar, New Delhi 110073 South West DELHI 110073 India
	Phone	9560659728
	Fax	
	Email	addl.director.academics@gmail.com
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr N R Singh
	Designation	Professor and HOD- Kayachikitsa, Additional Director Academics
	Affiliation	Chaudhary Bahm Prakash Ayurved Charak Sansthan, New Delhi
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	India			
Phone	9560659728			
Fax				
Email	addl.director.academics@gmail.com			
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Central Council for Research in Ayurvedic Sciences (C.C.R.A.S.), New Delhi			
Primary Sponsor	Primary Sponsor Details			
Name	Central Council for Research in Ayurvedic Sciences CCRAS			
Address	Jawahar Lal Nehru Bhartiya Chikitsa Evam Homoeopathy Anusandhan Bhawan 61-65, Institutional Area, Opposite D-Block, Janakpuri, New Delhi-110058			
Type of Sponsor	Research institution			
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
	Dr Vidula Gujarwar	Ch. Brahm Prakash Ayurved Charak Sansthan, New Delhi	CBPACS,director office, Khera Dabar, Najafgarh New Delhi 110073 South West DELHI	9990174348 cbpayurved@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Institutional Ethics Committee-CBPACS	Approved	25/05/2020	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Patients		Coronavirus as the cause of diseases classified elsewhere	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Ayush-64, a polyherbal formulation.	The composition of AYUSH 64 includes aqueous extract of Saptaparna (Alstoniascholaris R. Br.) Katuki (Picrorhizakurroa Royle ex. Benth), Kiratatikta (SwertiaChirataPexbex. Karst) and powder of Kuberaksha (Caesalpinia crista Linn.) in the ratio of 1:1:1:2.Dose:- 2 Tablets (500 mg) thrice daily (2-2-2) Dosage form:- Tablet Route of Administration:- Oral Time of Administration:-after food Anupana:- Warm water Duration of therapy:- 14 days	
	Comparator Agent	Not applicable	Not applicable	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		



Age To	65.00 Year(s)
Gender	Both
Details	Mild to moderate cases registered in CHC CBPACS above 18 years of age, with COVID 2019 (Confirmed by RT-PCR) Participants who can take medicines orally Patients willing to provide signed informed consent

Exclusion Criteria

Exclusion Criteria	
Details	Cases of severe vomiting which would make oral administration of medicine difficult. Cases of respiratory failure and requiring mechanical ventilation. Alanine Transaminase (ALT) or Aspartate Transaminase (AST) > 2 times the upper limit of normal. Patients with COVID 19 in critical condition or ARDS or NIAD 8 –point ordinal score 2 Hospitalized, on invasive mechanical Ventilation or extra corporeal membrane oxygenation Pregnant or lactating women Any other condition, which as per the investigator would jeopardize the outcome of the trial.

Method of Generating Random Sequence

Not Applicable

Method of Concealment

Not Applicable

Blinding/Masking

Not Applicable

Primary Outcome

Outcome	Timepoints
a) Mean time (days) for clinical recovery as per clinical recovery criteria defined below b) Number of patients showing 'clinical recovery'	Baseline Day 8 Day 15

Secondary Outcome

Outcome	Timepoints
1.Percentage of patients with negative SARS-CoV-2 on nasal or throat swab in a 2 day continuous real time RT-PCR test. 2.Improvement in selected laboratory parameters:, differential and total leukocyte counts, acute phase reactants, serum IL-6, Serological Protective Antibody Assay (IgE ,IgM and IgG) 3.Changes in liver enzymes, Renal functions 4.No of cases Reporting any ADR/AE 5.Number of participants referred with onset of complications	Baseline 8th day 15th day

Target Sample Size

Total Sample Size=40 Sample Size from India=40 Final Enrollment numbers achieved (Total)=0 Final Enrollment numbers achieved (India)=37
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Phase of Trial

Phase 3

Date of First Enrollment (India)

20/06/2020

Date of First Enrollment (Global)

No Date Specified

Estimated Duration of Trial

Years=0 Months=3 Days=5
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Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	Under process.
Brief Summary	<p>The experimental studies of AYUSH 64 has shown that it was safe and non-toxic in the dose of 500 mg/kg of body weight for 12 weeks. It is found to be effective in fevers of unknown etiology, filarial lymphangitis and derangement of liver function besides its anti-malarial activity. Taking leads from the clinical experiences of physicians who had successfully used AYUSH 64, for management of Influenza like Illness (ILI), a pilot study was conducted by CCRAS, which concluded recently and is under the process of publication. This study was done in 34 cases of flu like illness, wherein Ayush 64 helped to recover from ILI symptoms with reduced frequency of usage of acetaminophen and antihistaminic. This lead to the idea of repurposing AYUSH 64 for use in the management of COVID positive cases. So a single arm, open, prospective, non-controlled, interventional pilot study was conducted at Chaudhary Brham Prakash Ayurved Charak Sanstha (CBPACS), Khera Dabar, Najafgarh. A total of 64 patients of either sex above 18 years of age, confirmed cases of COVID 19 disease have been screened for taking 40 patient and 37 patients were enrolled in the study. The enrolled patients were assessed at baseline, 8th day and 15th day after their enrolment in the study. Out of 37 patients, 4 were drop out and rest 33 completed the study. Out of the completed 33 patients, 18 patients became COVID negative on 8th day and 7 patients became COVID negative on 15th day. 8 patients were those, who were COVID positive after completion of the trial.</p>