Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 11:37:11 GMT)

CTRI Number	CTRI/2020/05/025335 [Registered on: 24/05/2020] - **Trial Registered Prospectively**
Last Modified On	25/05/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Ayurveda
Study Design	Single Arm Trial
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
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Details Contact Person (Scientific Query)

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Name	Dr N R Singh
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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 Gujjarwar	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 beginning from ‘first day of clinical recovery’ or ‘Day 8th after onset of symptoms depending on whichever of the two time points is first achieved 2. Improvement in selected laboratory parameters:,	Baseline Day 8 Day 15

Target Sample Size	**Total Sample Size=**40 **Sample Size from India=**40 **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 3
Date of First Enrollment (India)	31/05/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**3 **Days=**5
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of	Not Yet Recruiting

Trial (India)	
Publication Details	Nil
Brief Summary	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.