



Clinical Trial Details (PDF Generation Date :- Tue, 27 Jul 2021 06:56:53 GMT)

CTRI Number	CTRI/2020/09/027974 [Registered on: 22/09/2020] - Trial Registered Prospectively	
Last Modified On	21/10/2020	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Drug Ayurveda	
Study Design	Randomized, Parallel Group Trial	
Public Title of Study	Clinical Evaluation of Chyawanprash for the prevention of COVID-19 among Health Care Personnel .	
Scientific Title of Study	Clinical Evaluation of Chyawanprash for the prevention of COVID-19 among Health Care Personnel – An open label, prospective Randomized controlled 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	
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> CCRAS New Delhi			
Primary Sponsor	Primary Sponsor Details			
	Name	Central Council for Research in Ayurvedic Sciences CCRAS		
	Address	Jawahar Lal Nehru BhartiyaChikitsaEvam Homoeopathy AnusandhanBhawan 61-65, Institutional Area, Opposite D-Block, Janakpuri New Delhi-110058		
	Type of Sponsor	Government funding agency		
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
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Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	King Georges Medical University U.P. Institutional Ethics Committee Lucknow226003	Approved	02/09/2020	Yes
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Healthy Human Volunteers		Negative for SARS- Cov-2	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Standard Preventive Regimen plus Ayurveda Rasayana (Chyawanprash)	Standard Preventive Regimen for healthcare workers(Standard precaution, Hand hygiene, Personal protective equipment , Respiratory hygiene and cough etiquette.) and Chyawanprash, Dose, 12gm twice daily Ayurvedic Formulation will be assessed in separate drug trial studies with a randomized two arm parallel design as per protocol.	
	Comparator Agent	Standard care as per the Ministry of health and family welfare guidelines for COVID19 and Updated	Standard Preventive Regimen for healthcare workers(Standard precaution, Hand hygiene, Personal protective equipment , Respiratory hygiene and cough etiquette.)	



Inclusion Criteria	Inclusion Criteria	
	Age From	25.00 Year(s)
	Age To	60.00 Year(s)
	Gender	Both
	Details	All healthcare professionals and staff of age group between 25 to 60 years willing to participate, negative for SARS- Cov-2 at screening,(tested by rt-PCR), at KGMU , without co-morbid condition with exposure/chance of exposure to COVID 19 positive cases. Who are willing to provide signed informed consent. High Risk Group- It includes doctors, nursing staff and other paramedical staff like attendant who are directly looking after and examining COVID patients. Low risk- other faculty members who are present in the institute but not visiting corona ward.
Exclusion Criteria	Exclusion Criteria	
	Details	Pregnant and lactating females. Immune compromised and co morbid condition cases. Laboratory confirmed COVID-19 with or without symptoms Known allergy to any of the medications used in this trial. Not willing to participate in the study. Subjects who are taking any other medicine as prophylaxis such as HCQ.
Method of Generating Random Sequence	Permuted block randomization, fixed	
Method of Concealment	Not Applicable	
Blinding/Masking	Open Label	
Primary Outcome	Outcome	Timepoints
	Percentage of participants with SARS- Cov-2 positivity as estimated by RT-PCR of nasopharyngeal swab / Chemiluminiscence assay after 1 month of consuming Chyawanprash.	Baseline, 7th day,15th day,and 30th day
Secondary Outcome	Outcome	Timepoints
	Safety profile of the intervention as estimated by LFT, KFT and other haematological & biochemical investigations. Presence or absence of AE/ADR. Number of participants who developed any infective diseases during the trial period (bacterial /viral/ fungal / etc.) and percentage of participants with Upper respiratory tract illness during the period. Immune and inflammatory markers (IgG, IgM, IgE, Hs-CRP TNF - ?,IL6, IL10) baseline and end of treatment.	Baseline ,on 7th day,on 15th day,and completion of study 30th day.
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 2	
Date of First Enrollment (India)	15/10/2020	
Date of First	No Date Specified	



Enrollment (Global)	
Estimated Duration of Trial	Years=0 Months=4 Days=0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NIL
Brief Summary	<p>COVID-19 has emerged as the latest pandemic that erupted in the Wuhan City of People’s Republic of China in December 2019, which is affecting human health and economy across the world. 1 133758 cases has been reported globally as on April 5, according to the WHO Coronavirus disease 2019 (COVID-19) Situation Report – 76. The occurrence of the ongoing COVID-19 in developed countries also highlights the fact that developed countries and rich populations are not immune to the outbreaks of infectious diseases. Coronaviruses (CoVs) belong to the family Coronaviridae and are enveloped, single-stranded, positive-sense RNA viruses. The SARS-CoV-2 belongs to the beta CoV genus which also includes the SARS-CoV-1 and the MERS-CoV. The lack of approved effective drug therapeutic protocols for CoVs would be a challenge for the treatment of the newly emerged COVID-19 infections worldwide. Drug repurposing, which is defined as identifying alternative uses for approved or investigational drugs outside their defined indication, could be a possible way to overcome the time limitation of research and development needed to design a therapeutic drug to combat the pathogen. The drug repurposing or repositioning approach thus can facilitate prompt clinical decisions at lower costs than de novo drug development.¹ Though drug repurposing is sometimes based on chance observations, target-based repurposing of drugs depends on prior understanding of the precise molecular or cellular element that is recognized by the proposed drug,^{2,3} Ayurveda and traditional systems of Medicine in India have been treating diseases of infectious and non-infectious origin equally with expansive success rates, treating the patients through an individualized person to person approach depending upon the presentation of clinical symptoms in each.</p> <p>Chyawanprash is a 5000 year old <u>Ayurvedic</u> multi-herbal jam considered to be a <i>Rasayana</i> for all the tissues of the body. <i>Rasayana</i> translates to “path of essence” as it promotes systemic rejuvenation of the mind and body. Chyawanprash is a potent antioxidant paste, prepared through the synergistic blending of around 50 herbs and spices. Chyawanprash falls, by virtue of its consistency and form of dosage, under the category of Awaleha (electuaries/herbal jams), a group of Ayurvedic formulations.⁴</p>



Respiratory Health- Protect and Strengthens the Respiratory System

A regular intake of *Chyawanprash* strengthens the trachea–bronchial tree and hence improves the immunity and functioning of the respiratory system. It helps to treat respiratory infections, allergic cough, asthma, bronchospasm, rhinitis, seasonal or non seasonal respiratory disorders, common cold, and tuberculosis, and thus strengthens the respiratory system. It is also used as an adjunct to antitubercular drugs to augment their bioactivity and prevent their side effects⁵⁻⁷ In a randomized controlled trial (RCT), 90 pulmonary tuberculosis patients were treated with *Chyawanprash* 10 g, twice daily as an adjunct to antitubercular drugs. *Chyawanprash* augmented the bioactivity of antitubercular drugs and prevented their side effects. Cough, expectoration, weakness, loss of appetite, loss of weight, fever, edema aches, and hemoptysis disappeared almost completely in the treated group, along with improvement in the hemoglobin (Hb) levels and effective healing as evidenced through chest X-ray post-therapy.^{5,8} Another observational study on 99 newly diagnosed pulmonary tuberculosis patients revealed that concomitant adjunct use of CP with antitubercular drugs significantly abated the symptoms and improved bioavailability of isoniazid and pyrazinamide.⁷

Antioxidant, Adaptogenic, and Immune-Booster

Recent investigations have ascertained that polyphenols (gallic acid, catechin, epicatechin) in CP exert key antioxidant potential and is known to possess potent neuroprotective, cytoprotective, and antioxidant properties.^{9,10} *Chyawanprash* is an effective adaptogenic.¹¹ Some clinical reports do support the adaptogenic and antioxidant effect of *Chyawanprash* on normal and depressive subjects.¹² Due to the rich Amla percentage, *Chyawanprash* is loaded in high vitamin C, polyphenolics, including flavonoids, and exhibits evident antioxidant and free radical scavenging activity, enhances the immune system, and fights infections.¹³ In a 6-month-long randomized, open labelled, prospective, multicenter, clinical study in children (5–12 years), CP was shown to lead to significant improvement in immunity, energy levels, physical strength, vigor, and quality of life assessed through KIDSCREEN QOL-27 questionnaires in children.¹⁴ Clinical studies support the immune-booster role of *Chyawanprash* as demonstrated by reduced disease symptoms of seasonal influences, modulated IgE and immunity markers C3 and C4 levels, improved pulmonary functions, decreased cortisol levels, and increased quality of life (QoL).¹⁵



The minute quantities of spice components of *Chyawanprash* are also known for their wide range of health benefits by their antioxidative, chemopreventive, antimutagenic, anti-inflammatory, immune-modulatory effects on cells and several beneficial effects on the gastrointestinal, cardiovascular, respiratory, metabolic, reproductive, neural, and other systems.¹⁶

Chyawanprash: A Nutraceutical and Functional Food

Chyawanprash has been a consistent part of Indian tradition both as a functional food and nutraceutical for the past 5000 years, with constant zeal and vivacity, and has survived owing to its peerless health benefits. Chyawanprash is reported to have rich vitamin, protein, dietary fiber, energy contents, carbohydrate, low fat contents (no-trans and zero percent cholesterol), and appreciable levels of major and minor trace elements (mg/100g), such as Fe (21.1), Zn (3.1), Co (3.7), Cu (0.667), Ni (1.4), Pb (2.4), Mn (8.3), vitamin C (0.5), tannic acid (20.2), other vitamins A, E, B1, B2, and carotenoids that act as micronutrients for health-invigorating purposes. It also provides several essential phytoconstituents, namely, flavonoids, alkaloids, saponins, antioxidants, piperine, phenolic compounds, etc. The synergistic antioxidant effects of vitamin C along with vitamin E and carotenoids are well known. The rich nutritive composition and antioxidant biomolecules of CP act both singly as well as synergistically for immuno-modulation, body building, health restoration, and prevention of oxidative damage (a leading cause of several degenerative diseases)