Clinical Trial Details (PDF Generation Date :- Sat, 03 Jun 2023 10:00:48 GMT)

CTRI Number	CTRI/2021/01/030454 [Registered on: 14/01/2021] - **Trial Registered Prospectively**
Last Modified On	12/08/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Ayurveda
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Clinical study on Zandu Chyavanprash as a preventive remedy in pandemic of Covid-19.
Scientific Title of Study	Clinical evaluation of Zandu Chyavanprash as an immunity booster for its preventive effect on infections in pandemic of COVID-19 – An open label, Multi centric, Randomized, Comparative, Prospective, Interventional Community based Clinical Study on Healthy individuals

Secondary IDs if Any

Secondary ID	Identifier
ZCP-CVD-19/2020/01 Version 1.0 Dated 20th Dec 2020	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
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Designation	Dean
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Emami Ltd, 687, Annadapur, EM Bypass, Kolkata-700107

Primary Sponsor

Primary Sponsor Details	
Name	Emami Ltd
Address	687, Annadapur, EM Bypass, Kolkata-700107
Type of Sponsor	Pharmaceutical industry-Indian

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 Shishir Pande	Ayurved Seva Sanghs Ayurved Mahavidyalaya	OPD No 7A, Ground Floor, Ayurved Sanshodhan Vibhag, Ayurved Seva Sanghs Ayurved Mahavidyalaya, Ganeshwadi, Panchvati, Nashik – 422003 Nashik MAHARASHTRA	9420830818 shishir.nsk@gmail.com
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		MAHARASHTRA	
Dr Shailesh Deshpande	Parul Ayurveda Hospital, Parul University	Department of Kaychikitsa, OPD no 106, Ground Floor, Parul Ayurveda Hospital, Parul University, P.O.Limba, Tal. Wagholia, Dist, Vadodara, Gujrat 391760 Vadodara GUJARAT	9763104451 dr.shaileshd@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee –D Y Patil University, School of Ayurveda, Nerul, Mumbai	Approved	16/01/2021	No
Institutional Ethics Committee PIAR-IECHR	Approved	09/01/2021	No
Institutional Ethics Committee, Ayurved seva sangh Ayurved Mahavidyalaya, Nashik	Approved	16/01/2021	No
Institutional Review Board For Research, MAMs SS Ayurveda Mahavidyalaya & Sane Guruji Aarogya Kendra, Malwadi, Hadapsar, Pune	Approved	01/02/2021	No
Parul Institute of Ayurved and Researchs Institutional Ethics Committee for Human Research (PIA-IECHR	Approved	09/01/2021	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Immunity in Healthy Individuals

Intervention / Comparator Agent

Type	Name	Details
Intervention	Zandu Chyavanprash and Milk	Zandu Chyavanprash contains Bilva, Agnimantha, Syonaka, Patala, Gambhari, Shalaprani, Prishniparni , Brihati, Kantakari, Gokshura, Bala, Mudgaparni, Mashaparni, Karkatshringi, Tamalaki, Draksha , Jivanti, Pushkara Haritaki ,Guduchi, Vidari, Musta , Rakta Punarnava, Vasa, Kakanasika, Pippali, Sukshmaila, Riddhi &Vriddh, Meda & Mahamedha, Jivaka & Rishabhak, Kakoli &

		Kshir kakoli. Powder of the Following: Pippali , Vanshalochana, Tvak, Tvakpatra, Sukshmaila, Nagakesara , Amalaki, Til tail, Ghrita, Guda, Honey along with preservatives and excipients Dosage and Treatment Duration:Subjects will be given Zandu Chyavanprash in a dose of one teaspoonful approx.12 gm) twice daily followed by a cup of milk (Approx. 200 ml).
Comparator Agent	Milk	Milk Dosage and Treatment Duration: Subjects will be asked to take a cup of milk twice daily (Approx. 200 ml) and will not be given any intervention

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	70.00 Year(s)
Gender	Both
Details	1. Healthy individuals will be considered as those who do not have any acute medical condition or chronic medical or surgical condition that requires either immediate or continuous medical monitoring or treatment. 2. Subjects tested Negative for total antibodies for COVID-19 3. Subjects who are ready to provide written informed consent and who are ready to willingly participate and follow the protocol requirements of the clinical study.

Exclusion Criteria

Exclusion Criteria	
Details	1.Pregnant and Lactating females 2. Subjects who have been confirmed of having COVID-19 and have been isolated for its treatment. Subjects having recently suffered and recovered of COVID-19 will also be excluded from the study 3. Known cases of Diabetes 4. Subjects having any medical or surgical condition that would require immediate medical or surgical intervention at the time of screening 4. Subjects having immune compromised status like HIV, Hepatitis, Tuberculosis and Cancer etc. 5. Subjects taking steroid treatment and or any kind of immunosuppressive therapy 6. Subjects participating in any other clinical study or having participated in any other study 3 months prior to screening in the present study. 7. Subjects having a past history of allergy to Chyawanprash like products 8. Other conditions, which in the opinion of the investigators makes the patient unsuitable for enrolment or could interfere in adherence to of the study protocol

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Not Applicable
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints

1. Change in incidence of COVID-19 [by RT-PCR and or total antibody fo r[COVID-19] in subjects taking Zandu Chyavanprash and those not taking it 2. Change in incidence of other non COVID-19 infections in subjects taking Zandu Chyavanprash and those not taking it	Screening visit (day -5), baseline visit (day 0), day 15, day 30, day 45, day 60, day 75 and day 90.

Secondary Outcome

Outcome	Timepoints
1. Change in severity of COVID-19 (when it occurs) between two groups 2. Change in number of subjects requiring hospitalization etc between two groups. 3. Change in ordinal scale for clinical improvement of COVID-19 between two groups 4. Change in incidence and severity of other allergy related health between two groups 5. Changes in Quality of life between two groups 6. Change in global assessment for overall change as per the investigator 7. AE and SAE assessment	Screening visit (day -5), baseline visit (day 0), day 15, day 30, day 45, day 60, day 75 and day 90.

Target Sample Size	**Total Sample Size=**300 **Sample Size from India=**300 **Final Enrollment numbers achieved (Total)=**0 **Final Enrollment numbers achieved (India)=**0
Phase of Trial	Phase 2/ Phase 3
Date of First Enrollment (India)	22/01/2021
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**8 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	Not yet done
Brief Summary	It is an open label, multi centric, randomized, comparative, prospective, interventional, community based, clinical study on healthy individuals to evaluate efficacy and safety of Zandu Chyavanprash as an immunity booster for its preventive effect on infections in pandemic of COVID-19. The study will be carried out at 5 centres in India. As per computer generated randomization list, subjects will be divided in group A or group B. Subjects in group A will be given Zandu Chyavanprash in a dose of one teaspoonful approx.12 gm) twice daily followed by a cup of milk (Approx. 200 ml). Subjects in Group B will be asked to take a cup of milk twice daily (Approx. 200 ml) and will not be given any intervention. The primary objectives of the study will be to assess comparative incidence of COVID-19 [by RT- PCR and/or total antibody for [COVID-19] in subjects taking Zandu Chyavanprash and those not taking it over a period of 3 months (90 days) and comparative incidence of other non COVID-19 infections in subjects taking Zandu Chyavanprash and those not taking it

over a period of 3 months (90 days). The secondary objectives will be comparative assessment of severity of COVID-19 (when it occurs) in subjects taking Zandu Chyavanprash and those not taking it, comparative assessment of number of subjects requiring hospitalization, number of days of hospitalization, number of subjects requiring ICU admission and number of subjects requiring Ventilator support and mortality rate, comparative assessment of subjects in the two groups diagnosed with COVID-19 as per the ordinal scale for clinical improvement of COVID-19 published by WHO, comparative assessment of incidence and severity of other allergy related health problems like cough, sneezing, rhinitis, sore throat etc, comparative assessment of changes in Quality of life on WHO –BREF, global assessment for overall change as per the investigator (Efficacy assessment) and safety assessment by evaluation of occurrence of AE/SAE on screening visit (day -5), baseline visit (day 0), day 15, day 30, day 45, day 60, day 75 and day 90.