



Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 11:25:14 GMT)

CTRI Number	CTRI/2020/05/025398 [Registered on: 28/05/2020] - Trial Registered Prospectively	
Last Modified On	22/07/2020	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Drug Ayurveda Preventive	
Study Design	Single Arm Trial	
Public Title of Study	Study to find out the results of Ayurvedic Kwath & Ashwagandha churna with Yoga exercises to prevent our health workers against corona virus infection.	
Scientific Title of Study	Efficacy of Kiratiktadi Kwath & Ashwagandha churna with Yoga modalities in prevention of infection against COVID -19 in Front line Health care workers	
Secondary IDs if Any	Secondary ID	Identifier
	No	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Prof Dr Ankur Singhal
	Designation	Professor, Department Of Kayachikitsa,
	Affiliation	GS Ayurveda Medical College and Hospital, Pilkhuwa
	Address	GS AYURVEDA MEDICAL COLLEGE & HOSPITAL, NH-9, POST-PILKHUWA DISTRICT- HAPUR PIN-245304 Ghaziabad UTTAR PRADESH 245304 India
	Phone	09760768689
	Fax	
	Email	drankursinghal2015@gmail.com
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Prof Dr Ankur Singhal
	Designation	Professor, Department Of Kayachikitsa,
	Affiliation	GS Ayurveda Medical College & Hospital, Pilkhuwa
	Address	GS AYURVEDA MEDICAL COLLEGE & HOSPITAL, PILKHUWA Ghaziabad UTTAR PRADESH 245304 India
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	Affiliation	GS Ayurveda Medical College & Hospital, Pilkhuwa
	Address	GS AYURVEDA MEDICAL COLLEGE & HOSPITAL, POST-PILKHUWA DISTRICT-HAPUR Ghaziabad UTTAR PRADESH 245304 India



Phone	09760768689			
Fax				
Email	drankursinghal2015@gmail.com			
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> MANAGING DIRECTOR, GS AYURVEDA MEDICAL COLLEGE & HOSPITAL, PILKHUWA, HAPUR -245304			
Primary Sponsor	Primary Sponsor Details			
	Name	NO		
	Address	NIL		
	Type of Sponsor	Other [no]		
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 Ankur Singhal	GS Ayurveda Medical College & Hospital	DEPARTMENT OF KAYACHIKITSA, GS AYURVEDA MEDICAL COLLEGE & HOSPITAL, NH-9, Near Pilkhuwa Railway Station, Pilkhuwa , District-Hapur Ghaziabad UTTAR PRADESH	09760768689 drankursinghal2015@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	IEC	Approved	18/05/2020	Yes
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Healthy Human Volunteers		HEALTHY	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	1) Kiratiktadi Kwath(Astadashang Kwath) for 14 days 2) Ashwgandha churna for 14 days 3) Yoga Modalities for 45 minutres	1) Kiratiktadi Kwath (Astadashang Kwath) 30 ml twice a day empty stomach.ref-Sharangdhar Samhita -kwath prakaran - for 14 days 2)Ashwgandha churna 5gm with Milk Before sleep. for 14 days 3) Yoga modalities for 45 min twice a day empty stomach	
	Comparator Agent	NIL	NIL	
Inclusion Criteria	Inclusion Criteria			
	Age From	20.00 Year(s)		
	Age To	60.00 Year(s)		
	Gender	Both		
	Details	Inclusive criteria		



	Asymptomatic healthy cases appointed as front line health care workers. Age above 20 yrs or below 60 yrs of either sex.	
Exclusion Criteria	Exclusion Criteria	
Details	Exclusive Criteria Cases suffering from any co morbidities. Age below 20 or above 60 yrs Cases those are symptomatic to COVID-19 before study.	
Method of Generating Random Sequence	Not Applicable	
Method of Concealment	Not Applicable	
Blinding/Masking	Not Applicable	
Primary Outcome	Outcome	Timepoints
	1) Efficacy of Kiratiktadi Kwath & Ashwagandha Churna with Yoga modalities in boosting Vyadhikshamatwa and prevention against communicable diseases. 2) Will help in overcoming the anxiety level and stress of healthcare workers.	4 weeks
Secondary Outcome	Outcome	Timepoints
	Will help in overcoming the anxiety level and stress of healthcare workers.	4 weeks
Target Sample Size	Total Sample Size=30 Sample Size from India=30 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)	28/05/2020	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=0 Months=0 Days=30	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Open to Recruitment	
Publication Details	NIL	
Brief Summary	This research has been proposed to assess the efficacy of Kiratiktadi Kwath & Ashwagandha churna with Yoga modalities in Health care workers taking care of COVID-19 patients.	