



Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 10:24:35 GMT)

<b>CTRI Number</b>	CTRI/2020/05/025341 [Registered on: 24/05/2020] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	22/07/2020	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Ayurveda Yoga & Naturopathy	
<b>Study Design</b>	Randomized, Parallel Group Trial	
<b>Public Title of Study</b>	A study to know the effect of Ayurvedic Kwath(Kiratiktadi Kwath) & Ashwagandha Churna along with yoga exercises in the treatment of COVID-19 Positive patients.	
<b>Scientific Title of Study</b>	Efficacy of Kiratiktadi Kwath & Ashwagandha Churna with Yoga modalities in management of COVID -19 patients.	
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>
	NIL	NIL
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>	
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> Mrs. Sonali Sharma, The Managing Director GS Ayurveda Medical College & Hospital, Pilkhuwa District-Hapur			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
	<b>Name</b>	NO		
	<b>Address</b>	NIL		
	<b>Type of Sponsor</b>	Other [Nil]		
<b>Details of Secondary Sponsor</b>	<b>Name</b>	<b>Address</b>		
	NO	NIL		
<b>Countries of Recruitment</b>	<b>List of Countries</b>			
	India			
<b>Sites of Study</b>	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>
	Dr Ankur Singhal	GS Ayurveda Medical College & Hospital	GS Ayurveda Medical College & Hospital, NH-9, Near Railway Station, Post-Pilkhuwa, District-Hapur Ghaziabad UTTAR PRADESH	09760768689 drankursinghal2015@gmail.com
<b>Details of Ethics Committee</b>	<b>Name of Committee</b>	<b>Approval Status</b>	<b>Date of Approval</b>	<b>Is Independent Ethics Committee?</b>
	IEC	Approved	21/05/2020	No
<b>Regulatory Clearance Status from DCGI</b>	<b>Status</b>		<b>Date</b>	
	Not Applicable		No Date Specified	
<b>Health Condition / Problems Studied</b>	<b>Health Type</b>		<b>Condition</b>	
	Patients		Coronavirus as the cause of diseases classified elsewhere	
	Patients		Coronavirus infection, unspecified	
	Patients		Other specified viral diseases	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	1) Kiratiktadi Kwath 30 ml twice a day before food for 14 days. 2) Ashwagandha churna 5gm before sleep with luke warm water. for 14 days 3) Yoga exercises 45 min twice a day empty stomach for 14 days. 4) Immunobooster Ayush Kwath as ministry of ayush guidelines 40 ml once a day (early morning , empty stomach)	1) Kiratiktadi Kwath as mentioned in sharngdhar samhita in kwath prakaran. 2) Aswagandha churna as mentioned in rasayan adhikar in chakradatt tika. 3) Yoga exercises including pranayam, suryanamaskar etc. as per MDNIY, NEW DELHI	
Comparator Agent	MODERN TREATMENT as per UP Govt Norms to asymptomatic and mild cases.	MODERN TREATMENT as per UP Govt Norms to asymptomatic and mild cases.		



<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>	
	<b>Age From</b>	20.00 Year(s)
	<b>Age To</b>	60.00 Year(s)
	<b>Gender</b>	Both
	<b>Details</b>	1) COVID 19 positive cases with mild symptoms or Asymptomatic 2) Age: above 20 yrs or below 60 yrs of either sex.
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>	
	<b>Details</b>	1) Cases suffering from any co morbidities. 2) Age below 20 or above 60 yrs COVID -19 negative cases. 3) If the patient develops any systemic side effects. Symptoms of COVID-19 aggravated to moderate level during study. 4) Moderate and Severe patients of COVID-19
<b>Method of Generating Random Sequence</b>	Not Applicable	
<b>Method of Concealment</b>	Case Record Numbers	
<b>Blinding/Masking</b>	Not Applicable	
<b>Primary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Efficacy of Kiratiktadi Kwath & Ashwagandha Churna with yoga modalities in the management of mild and asymptomatic cases of COVID-19 Patients	approx 12 weeks
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Rate of recovery with ayurvedic management as compared to modern treatment.	approx 12 weeks
<b>Target Sample Size</b>	<b>Total Sample Size=30</b> <b>Sample Size from India=30</b> <b>Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials</b> <b>Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials</b>	
<b>Phase of Trial</b>	N/A	
<b>Date of First Enrollment (India)</b>	02/06/2020	
<b>Date of First Enrollment (Global)</b>	No Date Specified	
<b>Estimated Duration of Trial</b>	<b>Years=0</b> <b>Months=3</b> <b>Days=0</b>	
<b>Recruitment Status of Trial (Global)</b>	Not Applicable	
<b>Recruitment Status of Trial (India)</b>	Open to Recruitment	
<b>Publication Details</b>	no	
<b>Brief Summary</b>	<p>EFFICACY OF KIRATIKTADI KWATH &amp; ASHWAGANDHA CHURNA WITH YOGA MODALITIES IN THE MANAGEMENT OF COVID-19 PATIENTS.</p> <p>Management includes:</p> <p>Guggulu dhoopan twice a day in COVID-19 wards.</p> <p>Ayush Kadha as herbal tea once a day early morning.</p> <p>Yoga sessions twice a day.</p>	



Kirtikatdi kwath 30 ml twice a day.

Ashwagandha churna 5gm once a day with lukewarm water.

Specific diet plan.