



Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 09:41:09 GMT)

CTRI Number	CTRI/2020/06/025592 [Registered on: 04/06/2020] - Trial Registered Prospectively	
Last Modified On	03/06/2020	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Drug Ayurveda	
Study Design	Single Arm Trial	
Public Title of Study	Use of Herbal Medicine like Tulasi, Amruth (Giloy), Turmeric, Ashwagandha as add on treatment in COVID-19 Patients	
Scientific Title of Study	A clinical Study to Evaluate the Role of Herbal Immunomodulators as add on Treatment in Asymptomatic and Mildly Symptomatic COVID-19 Confirmed 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 C R Jayanthi
	Designation	Director cum Dean BMCRI
	Affiliation	Bangalore Medical College research Institute
	Address	Bangalore Medical College research Institute Fort KR Road Bengaluru Department of COVID-19, Division - Isolation ward Room number - 1 Bangalore KARNATAKA 560002 India
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Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr C R Jayanthi
	Designation	Director cum Dean BMCRI
	Affiliation	Bangalore Medical College research Institute
	Address	Bangalore Medical College research Institute Fort KR Road Bengaluru Department of COVID-19, Division - Isolation ward Room number - 1 Bangalore KARNATAKA 560002 India
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Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Dr M Ravi Kumar Reddy
	Designation	Chief Scientific Officer
	Affiliation	Sri Sri Tattva
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Sriveda Sattva PvtLtd 54/56 39th A Cross 11th Main Road 4th T Block Jayanagar Bangalore Karnataka India 560041			
Primary Sponsor	Primary Sponsor Details			
Name	Sri Sri Tattva			
Address	Sriveda Sattva PvtLtd 54/56 39th A Cross11th Main Road 4th T BlockJayanagarBangaloreKarnatakaIndia560041			
Type of Sponsor	Pharmaceutical industry-Indian			
Details of Secondary Sponsor	Name	Address		
	Nil			
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Dr C R Jayanthi	Bangalore Medical college and research institute	Department of COVID-19, Division - Isolation ward Room number - 1 Fort KR road, Bangalore Bangalore KARNATAKA	9448292424 bmccrj@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Bangalore Medical college and research institute	Approved	16/05/2020	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	Immunity Kit	Shakti drops: Dosage: 5 drops 3 times a day (Morning/ Afternoon/Night) Amruth tablet: Dosage: 1 tablet 2 times a day Turmeric plus tablet:: Dosage: 1 tablet 2 times a day Tulsi arka: Dosage: 10 drops 3 times a day (Morning/ Afternoon/Night)	
	Comparator Agent	Not applicable	Not applicable	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		
	Age To	60.00 Year(s)		
	Gender	Both		



	Details	Confirmed Asymptomatic and mildly symptomatic cases of COVID-19 infection by laboratory tests Age limit 18 to 60 years both Male and Female Uncomplicated cases of COVID - 19 patients on Allopathic medication Patients in whom ventilator support is not required Patients with no associated co morbidities Patients willing to give informed consent to participate in the clinical trial
Exclusion Criteria	Exclusion Criteria	
	Details	COVID-19 positive patients above 60 years of age & below 18 years with Symptoms. Patients with associated comorbidities like hypertension, type 2 or type 1 diabetes mellitus, chronic or acute renal failure Patients on Immuno-suppression therapy Pregnant Women or lactating mothers Patients in advanced stage of disease requiring emergency medical intervention like pneumonia, bronchial asthma, organ failure
Method of Generating Random Sequence	Not Applicable	
Method of Concealment	Not Applicable	
Blinding/Masking	Open Label	
Primary Outcome	Outcome	Timepoints
	Early recovery in the signs and symptoms of cases of Asymptomatic and mild symptomatic COVID-19 patients by adding Ayurvedic medicines which are effective in enhancing immunity of body and reducing the symptoms such as Fever and respiratory distress	Day 1 and Day 30
Secondary Outcome	Outcome	Timepoints
	a. TNF-? b. IL-6 c. IFN- ? d. IFN-?	Day 1 and Day 30
Target Sample Size	Total Sample Size=50 Sample Size from India=50 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/ Phase 4	
Date of First Enrollment (India)	13/06/2020	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=0 Months=6 Days=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Not Yet Recruiting	
Publication Details	Not yet finalised on the journal in which the data from the current study would be published.	
Brief Summary		

Title: A clinical Study to Evaluate the role Herbal Immunomodulators as add on Treatment in Asymptomatic and Mildly Symptomatic COVID-19 Confirmed Cases.



This open Label, Comparative Interventional study conducted among 50 asymptomatic and mildly symptomatic COVID-19 confirmed patients, using Ayurveda Drugs:

SHAKTI DROPS: Dosage: 5 drops 3 times a day (Morning/Afternoon/Night)

AMRUTHI TABLET: Dosage: 1 tablet 2 times a day

TURMERIC PLUS TABLET: Dosage: 1 tablet 2 times a day

TULSI ARKA: Dosage: 10 drops 3 times a day (Morning/Afternoon/ Night)

Inclusion Criteria: Confirmed Asymptomatic and mildly symptomatic cases of COVID-19 infection by laboratory tests

Age: 18 to 40 years both Male and Female

Uncomplicated cases of COVID - 19 patients on Allopathic medication

Exclusion Criteria:

COVID-19 positive patients above 60 years of age & below 18 years with Symptoms.

Patients with associated comorbidities like hypertension, type 2 or type 1 diabetes mellitus, chronic or acute renal failure

Patients on immunosuppression therapy

Pregnant Women or lactating mothers Patients in advanced stage of disease requiring emergency medical intervention like pneumonia, bronchial asthma, organ failure

Primary Outcome: Early recovery in the signs and symptoms of cases of Asymptomatic and mildly symptomatic COVID-19 patients by using ayurvedic medicinal which are effective in enhancing immunity of body and reducing the symptoms such as Fever as Secondary outcome on Day 1 and Day 30
Secondary Outcome: TMP3, 4, 6, 8% 7, 8, 9% 7 on Day 1 and Day 30