Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 11:34:36 GMT)

CTRI Number	CTRI/2020/05/025254 [Registered on: 20/05/2020] - **Trial Registered Prospectively**
Last Modified On	24/07/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Unani
Study Design	Non-randomized, Multiple Arm Trial
Public Title of Study	To Study effectiveness and outcomes of Unani Medicine prophylactic interventions on population at risk of COVID-19
Scientific Title of Study	Population based Prospective Study on effectiveness and outcomes of Unani Medicine prophylactic interventions on population at risk of COVID-19

Secondary IDs if Any

Secondary ID	Identifier
CCRUM 05/2020/01 Version 1.0	Protocol Number

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

Details of Principal Investigator	
Name	Prof Asim Ali Khan
Designation	Director General
Affiliation	Central Council for Research in Unani Medicine (CCRUM)
Address	Room No 523, 5th Floor Jawahar Lal Nehru Bhartiya Chikitsa Evam Homoeopathy Anusandhan Bhawan, 61-65, Institutional Area, Opp. D Block, Janakpuri South West DELHI 110058 India
Phone	01128525715
Fax	
Email	unanimedicine@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Naheed Parveen
Designation	Assistant Director
Affiliation	Central Council for Research in Unani Medicine (CCRUM)
Address	Room No 507, 5th Floor Jawahar Lal Nehru Bhartiya Chikitsa Evam Homoeopathy Anusandhan Bhawan, 61-65, Institutional Area, Opp. D Block, Janakpuri South West DELHI 110058 India
Phone	9213511298
Fax	
Email	ccrum507@rediffmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Pradeep Kumar
Designation	Research Officer (Pathology) S-IV
Affiliation	Central Council for Research in Unani Medicine (CCRUM)
Address	Room No 516, 5th Floor Jawahar Lal Nehru Bhartiya Chikitsa Evam Homoeopathy Anusandhan Bhawan, 61-65, Institutional Area, Opp. D Block, Janakpuri South West DELHI

	110058 India
Phone	8800263300
Fax	
Email	drpradeepkumar2001@yahoo.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Monetary Support : Central Council for Research in Unani Medicine (CCRUM), New Delhi

Primary Sponsor

Primary Sponsor Details	
Name	Central Council for Research in Unani Medicine CCRUM New Delhi
Address	Jawahar Lal Nehru Bhartiya Chikitsa Evam Homoeopathy Anusandhan Bhawan, 61-65, Institutional Area, Opp. D Block, Janakpuri, New Delhi-110058.
Type of Sponsor	Research institution

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 Maqbool Ahmed	Central Research Institute of Unani Medicine (CRIUM)	Basaha, Kursi Road Lucknow UTTAR PRADESH	6386660524 ddcriumlko@gmail.com
Prof Abdul Wadood	National Institute of Unani Medicine (NRIUM)	National Institute of Unani Medicine Campus, Kottigepalya, Magadi Main Road Bangalore KARNATAKA	9916608881 crubangalore2000@gmail.com
Dr Ahmad Minhajuddin	National Research Institute of Unani Medicine in Skin Diseases (NRIUMSD)	A G Colony Road, Opposite ESI Hospital, Erragadda Hyderabad TELANGANA	9177376011 ahmedminhajuddin@yahoo.com
Dr Arsheed Iqbal	Regional Research Institute of Unani Medicine (RRIUM)	Naseem Bagh Campus, University of Kashmir Srinagar JAMMU & KASHMIR	9419078302 drarsheediqbal@gmail.com
Dr H A Lari	Regional Research Institute of Unani Medicine (RRIUM)	Behind Eye Bank, Sir J J Hospital Compound, Byculla Mumbai MAHARASHTRA	9335903933 halariccrum@gmail.com
Dr Parvez Khan	Regional Research Institute of Unani Medicine (RRIUM)	Post Box 70, Shahjahan Manzil, Near AMU Riding Club, Qila Road Aligarh UTTAR PRADESH	9411059371 rrium_aligarh@rediffmail.com
Dr Shagufta Parveen	Regional Research Institute of Unani Medicine (RRIUM)	D-11, Abul Fazal Enclave, Jamia Nagar South DELHI	9810068758 rridelhi@gmail.com

Details of Ethics

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics

Committee

			Committee?
Central Research Institute of Unani Medicine (CRIUM), Lucknow	Approved	11/05/2020	No
National Institute of Unani Medicine (NRIUM), Bangalore	Approved	11/05/2020	No
National Research Institute of Unani Medicine in Skin Diseases (NRIUMSD), Hyderabad	Approved	11/05/2020	No
Regional Research Institute of Unani Medicine (RRIUM), Aligarh	Approved	11/05/2020	No
Regional Research Institute of Unani Medicine (RRIUM), Mumbai	Approved	11/05/2020	No
Regional Research Institute of Unani Medicine (RRIUM), New Delhi	Approved	11/05/2020	No
Regional Research Institute of Unani Medicine (RRIUM), Srinagar	Approved	11/05/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	U07.1 COVID-19

Intervention / Comparator Agent

Type	Name	Details
Intervention	Unani Joshanda (Decoction)and Khameera Marwareed	Unani Joshanda (Decoction) lukewarm once daily in the evening and Khameera Marwareed 5g once daily in the morning for 20 days, for 10000 subjects. (Test group 1)
Intervention	Unani Joshanda (Decoction)and Tiryaq-e-Arba	Unani Joshanda (Decoction) lukewarm once daily in the evening,and Tiryaq e Arba 5g with lukewarm water in the morning for 20 days for 10000 patients. (Test group 1)
Comparator Agent	nil	nil

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	68.00 Year(s)
Gender	Both
Details	1. Individuals of either sex above 18 and below 68 years 2. Population as described in High/Moderate/Low Risk 3. Individuals who are from the identified containment zone/

	quarantine facility with at least 1 confirmed COVID-19 positive case. 4. Subjects who are ready to provide written/digital informed consent and who are willing to participate and follow the protocol requirements of the clinical study

Exclusion Criteria

Exclusion Criteria	
Details	1. Persons with severe primary respiratory disease or related complications that may be identified with COVID-19 2. Laboratory confirmed COVID-19 with or without symptoms 3. Pregnant and lactating mothers and those who have a pregnancy plan. 4. Persons with serious critical illness, or severe mental illnesses 5. Individuals with uncontrolled, unstable comorbidities 6. Immunocompromised individuals or those on immunosuppressants and steroids 7. Subjects having a past history of allergy to any medicine that is part of the Unani intervention.

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
Incidence of COVID-19 cases in control as well in interventional group 2.Improvement in immune status using Immune Status Questionnaire (ISQ)	20days

Secondary Outcome

Outcome	Timepoints
NIL	NIL

Target Sample Size	**Total Sample Size=**40000 **Sample Size from India=**40000 **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
Date of First Enrollment (India)	29/05/2020
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	NIL
Brief Summary	This study is designed as a multicentric open label, Controlled, Prospective, Interventional, Community-based trial to compare occurrence of COVID 19 infection in clinically stable subjects receiving Unani regimen with those not receiving Unani Regimen in a community having at least 1 confirmed case with standard prophylactic care as control, in the identified containment zone/ quarantine facility. The study will be carried out on a total sample size of 40,000 (forty thousand subjects). Ten thousand in test group 1 (Unani Joshanda (Decoction)and Khameera Marwareed) and Ten thousand in test group 2 (Unani Joshanda (Decoction)and Tiryaq e Arba) . And twenty thousand subjects will be enrolled in the control group and will be advised to follow general prophylactic measurements without any medicinal intervention. After screening, subjects will be enrolled if they satisfy inclusion and exclusion criteria. The patients will be assessed clinically at day 0 (baseline), day 10 (telephonic follow-up) and day 20 (end of the study). The subjective and objective clinical observations will be recorded in the CRF. This includes Assessment of Immune status Questionnaire (ISQ). The total duration of treatment will be 20days. Test for Covid-19 will be done at any time during the study (if the symptoms develop) as per the guidelines of the central/state or local health authority.

Details of study drugs

A. First group will be given:		
Unani Joshanda (Decoction) consisting of the following single drugs- • **Behidana (Cydonia oblonga) 3 gm** • **Unnab (Zizyphus jujube), 5 in number** • **Sapistan (Cordia myxa), 9 in numbers**		**Preparation of Decoction by boiling thes medicines in 250 ml of water, until remains half and filtered.** **To be used lukewarm once daily in th Evening.**
KhameeraMarwareed		**5 gm once daily in the morning**

B. Second group will be given:

Unani Joshanda (Decoction) consisting of the following single drugs- • **Behidana (Cydonia oblonga) 3 gm** • **Unnab (Zizyphus jujube), 5 in number** • **Sapistan (Cordia myxa), 9 in numbers**		**Preparation of Decoction by boiling these medicines in 250 ml of water, until remains half and filtered.** **To be used lukewarm once daily in the Evening.**

Tiryaq-e-Arba		**5 gm once daily with lukewarm water in th** **Morning**	

Composition of Khameera Marwareed:

S. No.	Ingredients	Botanical/ English Name	Quantity
1.	Marwareed	*Mytilus margaritiferus*	25g
2.	Tabasheer	*Bambusa arundinacea*	25g
3.	Sandal safaid	*Santalum album*	25g
4.	Ambar Ash-hab	*Ambra grasea*	10g
5.	Arq e Gulab	*Rosa damascena*	1Lit.
6.	Arq e Bedmushk	*Salix caprea*	1Lit.
7.	Qand safaid	Sugar	1.5kg

Composition of Tiryaq e Arba:

S. No.	Ingredients	Botanical/ English Name	Quantity

1.		Juntiyana	*Gentiana lutea*	1part
	2.	Zarawand taweel	*Aristolochia rotunda*	1part
	3.	Habb-ul-Ghar	*Laurus nobilis*	1part
	4.	Mur Makki	*Commiphora myrrha*	1part
	5.	Asl or Qand safaid	Honey/Sugar	Q.S.