

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The Effectiveness of Integrative Treatment Interventions on Covid-19 Patients: A Single Group, Pretest-Posttest clinical Trial

#### Protocol summary

##### Study aim

To find the effectiveness of integrative treatment of COVID-19 patients.

##### Design

Interventional study design. sample size 34, non-randomized single group pre post . phase 1 clinical trials

##### Settings and conduct

Knowledge Research and Innovation Center, Pakistan (KRIC) questionnaire pre and post treatment was filled by the patients.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria a. Both genders b. Aged between 18-80 years c. Mild, moderate or severe infection. d. COVID-19 positive on the basis of symptoms, physical test and lab test. Exclusion Criteria a. Any tumor or malignancy b. Recent surgery c. Patient on invasive / non-invasive ventilator (critical) d. Taking any other medicine parallel to PAK-20, Oniater and Hing for treatment of COVID-19. e. Taking any immunosuppressant

##### Intervention groups

Single intervention group. Methods: 34 COVID-19 patients (males and females) with mild to severe symptoms were given the Intervention. Baseline treatment; 1gm of PAK-20 in 250ml of Combo 1 (soup/meat stock) twice a day for a max of 12 days, 50 ml of Oniater (onion water) once a day for 3 days. Hing (Asafoetida) tempering added to daily food diet to address blood clotting, or coagulation. Supplementary treatment; Combo 2 (herbal tea), 250ml of twice a day for a maximum of 12 days. Datseed (date filled with black seeds, once a day for a maximum of 12 days. Use of protein heavy diets, fruits, milk shakes and fresh juices given even beyond 12 days. Use of 70gm of Talbina once per day, which served as high potency oral multivitamins energy diet.

##### Main outcome variables

1. Fever
2. Cough
3. Sore Throat
4. Shortness of Breath
5. Muscle Pain

#### General information

##### Reason for update

Minor change in Sub Title and few rearrangements of sentences

##### Acronym

COVID-19

##### IRCT registration information

IRCT registration number: **IRCT20200823048495N1**

Registration date: **2020-12-12, 1399/09/22**

Registration timing: **retrospective**

Last update: **2021-03-21, 1400/01/01**

Update count: **3**

##### Registration date

2020-12-12, 1399/09/22

##### Registrant information

###### Name

Umber Nawaz

###### Name of organization / entity

Knowledge Research and Innovation Center

###### Country

Pakistan

###### Phone

+92 42 35440889

###### Email address

umber@kric.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-17, 1398/10/27

##### Expected recruitment end date

2020-06-30, 1399/04/10

##### Actual recruitment start date

2020-03-17, 1398/12/27

##### Actual recruitment end date

2020-07-01, 1399/04/11

**Trial completion date**

2020-07-01, 1399/04/11

**Scientific title**

The Effectiveness of Integrative Treatment Interventions on Covid-19 Patients: A Single Group, Pretest-Posttest clinical Trial

**Public title**

COVID-19 Cure Using Integrative Treatment

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Both genders Aged between 18-80 years Mild, moderate or severe infection COVID-19 positive on the basis of symptoms, physical test and lab test

**Exclusion criteria:**

Any tumor or malignancy Recent surgery Patient on invasive / non-invasive ventilator (critical) Taking any other medicine parallel to PAK-20, Oniater and Hing for treatment of COVID-19. Taking any immunosuppressant

**Age**

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

1

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **39**

Actual sample size reached: **34**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids****1****Registry name**

World Health Organization Universal Trial Number

**Secondary trial Id**

U1111-1262-7419

**Registration date**

2020-12-15, 1399/09/25

**Ethics committees****1****Ethics committee**

**Name of ethics committee**

Ethical Research Committee of Knowledge Research and Innovation Center, Pakistan (KRIC)

**Street address**

9 Noon Avenue, Block C, Muslim Town, Canal Road, Lahore, Punjab, Pakistan

**City**

Lahore

**Postal code**

54000

**Approval date**

2020-03-16, 1398/12/26

**Ethics committee reference number**

KRIC/REC/1/01

**Health conditions studied****1****Description of health condition studied**

SARS-COV-2

**ICD-10 code**

B97.21

**ICD-10 code description**

SARS-associated coronavirus as the cause of diseases classified elsewhere

**Primary outcomes****1****Description**

Fever

**Timepoint**

Before intervention and (1,3,5) odd days after intervention

**Method of measurement**

Thermometer

**2****Description**

Cough

**Timepoint**

Before intervention and (1,3,5,7,9,11) odd days after intervention

**Method of measurement**

Cough Scale

**3****Description**

Sore Throat

**Timepoint**

Before intervention and (1,3,5,7,9,11) odd days after intervention

**Method of measurement**

Sore Throat Scale

**4****Description**

Shortness of Breath

### **Timepoint**

Before intervention and (1,3,5,7,9,11) odd days after intervention

### **Method of measurement**

Borg Scale of Short of Breath

## **5**

### **Description**

Muscle Pain

### **Timepoint**

Before intervention and (1,3,5,7,9,11) odd days after intervention

### **Method of measurement**

Numeric pain rating Scale

## **Secondary outcomes**

## **1**

### **Description**

PCR-RT for COVID-19

### **Timepoint**

Before intervention and 14th day after intervention

### **Method of measurement**

PCR-RT Lab test

## **2**

### **Description**

Chest X-ray

### **Timepoint**

Before intervention and on 14th day after intervention

### **Method of measurement**

Radiological X-ray findings

## **3**

### **Description**

10 Second Breath Hold Test

### **Timepoint**

Before intervention and on 14th day after intervention

### **Method of measurement**

Physical 10 Second breath Hold

## **Intervention groups**

## **1**

### **Description**

Single intervention group. Methods: 34 COVID-19 patients (males and females) with mild to severe symptoms were given the Intervention. Baseline treatment; 1gm of PAK-20 in 250ml of Combo 1 (soup/meat stock) twice a day for a max of 12 days, 50 ml of Oniater (onion water) once a day for 3 days. Hing (Asafoetida) tempering added to daily food diet to address blood clotting, or coagulation. Supplementary treatment; Combo 2 (herbal tea), 250ml of twice a day for a maximum of 12 days. Datseed (date filled with black seeds, once a day for a maximum of 12 days. Use of protein heavy diets, fruits, milk shakes and fresh

juices given even beyond 12 days. Use of 70gm of Talbina once per day, which served as high potency oral multivitamins energy diet.

### **Category**

Treatment - Drugs

## **Recruitment centers**

## **1**

### **Recruitment center**

#### **Name of recruitment center**

Knowledge Research and Innovation Center, Pakistan (KRIC)

#### **Full name of responsible person**

Muhammad Yahya Qureshi

#### **Street address**

9 Noon Avenue, Block C, Muslim Town, Canal Road, Lahore, Punjab, Pakistan

#### **City**

Lahore

#### **Postal code**

54000

#### **Phone**

+92 42 35440889

#### **Email**

yahya@kric.edu.pk

#### **Web page address**

<https://www.kric.edu.pk>

## **Sponsors / Funding sources**

## **1**

### **Sponsor**

#### **Name of organization / entity**

Knowledge Research and Innovation Center, Pakistan (KRIC)

#### **Full name of responsible person**

Muhammad Anwar Masood Behr

#### **Street address**

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#### **Phone**

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### **Grant name**

Knowledge Research and Innovation Center, Pakistan (KRIC)

### **Grant code / Reference number**

### **Is the source of funding the same sponsor organization/entity?**

Yes

### **Title of funding source**

Knowledge Research and Innovation Center, Pakistan

(KRIC)  
**Proportion provided by this source**  
100  
**Public or private sector**  
Private  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Other

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Knowledge Research and Innovation Center, Pakistan  
(KRIC)  
**Full name of responsible person**  
Umber Nawaz  
**Position**  
Researcher  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Prophetic Medicine  
**Street address**  
9 Noon Avenue, Block C, Muslim Town, Canal Road,  
Lahore, Punjab, Pakistan  
**City**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Knowledge Research and Innovation Center, Pakistan  
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Researcher  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Knowledge Research and Innovation Center  
**Full name of responsible person**  
Umber Nawaz  
**Position**  
Director Admin and coordination  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Herbal Medicine  
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<https://www.kric.edu.pk>

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

IPD collected for the primary and secondary outcome measures

### When the data will become available and for how

**long**

Starting 6 months after publication

**To whom data/document is available**

Data will be available globally

**Under which criteria data/document could be used**

Data will be accessible to the researchers for the future researches.

**From where data/document is obtainable**

The researchers can communicate on the following

website: <https://www.kric.edu.pk> or can email at:  
health@kric.edu.pk

**What processes are involved for a request to access data/document**

Communication from the research center, then send an application for the use of data along with cover letter and resume at: health@kric.edu.pk

**Comments**