

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

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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

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

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Email

behr@kric.edu.pk

Web page address

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

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

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Province

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Phone

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Web page address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Knowledge Research and Innovation Center, Pakistan
(KRIC)

Full name of responsible person

Umber Nawaz

Position

Researcher

Latest degree

Specialist

Other areas of specialty/work

Prophetic Medicine

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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

Street address

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umber@kric.edu.pk

Web page address

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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