Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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+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
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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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Postal code
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Phone
+92 42 35440889
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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9 Noon Avenue, Block C, Muslim Town, Canal Road, Lahore, Punjab, Pakistan

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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

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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