

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the effect of Traditional medicine product incorporated in the base of Astragalus gossypinus with food spice on improvement of clinical manifestation of COVID -19 patients with conventional protocol

Protocol summary

24 hours.

Study aim

Evaluation of the effect of Traditional Medicine product incorporated in the base of Astragalus gossypinus with food spice on improvement of clinical manifestation of COVID-19 patients with conventional protocol

Design

This study is a randomized, controlled, double-arm clinical trial. Eighty patients will be included in the study. Physicians who assess outcomes and the statistician analyzing the data all will be blinded

Settings and conduct

This study will be conducted in Kerman hospitals. In the intervention group, 40 patients with COVID-19 receive in addition to standard treatment, traditional medicine protocols including traditional syrup and food spice. Forty patients in the control group received standard treatment only.

Participants/Inclusion and exclusion criteria

Inclusion criteria: confirmed cases of COVID-19 infection with specialist on the base of CT and pharyngeal specimen; Exclusion criteria: Pregnancy, Breastfeeding

Intervention groups

Intervention group received standard treatment with traditional medicine protocol including traditional syrup based on Astragalus gossypinus a rate of 10 cc daily for two hours on the first and second days and 10 cc on the following days. Contemporary Patients receive 2 grams of herbal spice food with a apple juice daily after breakfast. Patients in the control group will receive only the standard treatment.

Main outcome variables

Significant clinical symptoms and vital signs : Clinical recovery up to 10 days from initiation of study treatment until normalization of fever (≤ 37.2 °C oral), respiratory rate (≤ 24 /minute on room air), and oxygen saturation ($>94\%$ on room air), and alleviation of cough (mild or absent on a patient reported scale), sustained for at least

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101219005416N2**

Registration date: **2020-04-03, 1399/01/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-03, 1399/01/15**

Update count: **0**

Registration date

2020-04-03, 1399/01/15

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

03412266914

Email address

h_tajadini@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-24, 1399/01/05

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Traditional medicine product incorporated in the base of Astragalus gossypinus with food spice on improvement of clinical manifestation of COVID -19 patients with conventional protocol

Public title

Evaluation of the effect of traditional Iranian medicine product on improvement of clinical manifestation of COVID -19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patients that confirmed COVID- 19 with specialist on the base of CT changing and pharyngeal specimen

Exclusion criteria:

Lack of informed consent Pregnancy Breastfeeding

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by permutation randomized block method in four-sided blocks. The construction of blocks is done with R version software 2, 3, 6.

Blinding (investigator's opinion)

Double blinded

Blinding description

The treatment assignment will remain unknown until the patient is randomized. Physicians who treat patients and the patients will not be blinded. Radiologists, physicians who assess outcomes and the statistician analyzing the data all will be blinded

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Deputy of Research and Technology;ebne-e-Sina St.,Jahad Blvd., Kerman,Iran

City

kerman

Province

Kerman

Postal code

7619813159

Approval date

2020-03-21, 1399/01/02

Ethics committee reference number

IR.KMU.REC.1399.003

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

Confirmed COVID-19

Primary outcomes

1

Description

Response to the treatment (Significant clinical improvement)

Timepoint

At baseline and daily

Method of measurement

According to the clinical, paraclinical and laboratory findings. Clinical improvement: normalization of the body temperature (≤ 37.2 ° C), respiratory rate (≤ 24 breaths per minute), oxygen saturation ($> 94\%$ at room temperature) and cough ; dyspnea ; headache and diarrhea that will measure on a qualitative scale based on the patient's report . Other outcome variables will measure during clinical examination.

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

End of the treatment

Method of measurement

Patient's medical record

2

Description

Mortality

Timepoint

End of the treatment

Method of measurement

Patient's medical record (Clinical outcome)

Intervention groups

1

Description

Intervention group: Patients admitted to hospital in addition to receiving standard treatments of the Corona Country Committee, received a traditional product based on Astragalus gossypinus of 10 cc daily for 2 hours and food spice based on Ferula assa-foetida of 2 grams once a day with apple juice. Traditional protocol duration is 5 days.

Category

Treatment - Drugs

2

Description

Control group: Hospitalized patients are receiving standard corona treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzali pour Hospital

Full name of responsible person

Haleh Tajadini

Street address

No. 9, Jahad Av19 ., Kerman

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drhalehtajadini@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abas Pardakhti

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Haleh Tajadini

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Haleh Tajadini

Position

Assistant professor

Latest degree

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Other areas of specialty/work

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