

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the effect of traditional medicine protocol included Astragalus gossypinus with Ferula assa capsule on improvement of COVID-19 outpatients symptoms treated with conventional protocol

Protocol summary

Study aim

Determining the effect of traditional medicine protocol included Astragalus gossypinus with Ferula assa capsule on improvement of COVID-19 outpatients symptoms with conventional protocol

Design

This study is a randomized, controlled, double-arm clinical trial. 120 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 out patirnt clinic. In the intervention group, 60 patients with COVID-19 receive in addition to standard treatment, traditional medicine protocol included traditional syrup and capsule . 60 patients in the control group received standard treatment only.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 80 years and having informed consent and lack of allergy to herbal medicines protocol, confirmation of COVID-19 by a specialist based on CT scan or diagnosis of disease from the throat sample or clinical signso

Intervention groups

The Intervention group receive standard treatment with traditional medicine protocol included traditional syrup based on Astragalus gossypinus at a rate of 10 cc daily for two hours on the first and second days . Simultaneously with this syrup Patients receive two capsule of Ferula assa (500mg) daily .Patients in the control group 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 alleviation of cough (mild or absent on a patient reported scale), sustained

for at least 24 hours.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101219005416N3**

Registration date: **2020-08-26, 1399/06/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-26, 1399/06/05**

Update count: **0**

Registration date

2020-08-26, 1399/06/05

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

2020-08-10, 1399/05/20

Expected recruitment end date

2020-09-10, 1399/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of traditional medicine protocol included Astragalus gossypinus with Ferula assa capsule on improvement of COVID-19 outpatients symptoms treated with conventional protocol

Public title

Effect of traditional medicine protocol included Astragalus gossypinus with Ferula assa capsule on improvement of COVID-19 outpatients symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

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

Exclusion criteria:

Lack of informed consent, Pregnancy, Breastfeeding

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

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,

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Kerman University of Medical Sciences

Street address

Deputy of Research and Technology, Ebn-e-Sina Ave., Jahad Blvd., Kerman

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2020-08-05, 1399/05/15

Ethics committee reference number

IR.KMU.REC.1399.275

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

Based on clinical, paraclinical and laboratory findings. Clinical improvement: normalization of the body temperature (≤ 37.2 ° C), respiratory rate (≤ 24 breaths per minute), 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

Mortality

Timepoint

End of the treatment

Method of measurement

Ratio of the number of deaths to total patients in each group

2

Description

Hospital admission

Timepoint

End of the treatment

Method of measurement

Ratio of the number of admission to total patients in each group

Intervention groups

1

Description

Control group: Hospitalized patients are receiving standard corona treatment

Category

Treatment - Drugs

2

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 3 hours and two Ferula assa-foetida capsule of 500mgr daily. Traditional protocol duration is 5 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Clinic

Full name of responsible person

Haleh Tajadini

Street address

Besat Clinic, Jahad Blvd., Kerman

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7619837773

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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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Ebn-e-Sina St, Jahad Blvd, Kerman

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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

80

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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Position

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

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Full name of responsible person

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Position

Assistant Professor

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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