Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

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

Protocol summary

Study aim

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

Public title
Effect of traditional medicine protocol included Astraglus 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; headche and dirrhea 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 admssion

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
City
Kerman
Province
Kerman
Postal code
7619837773
Phone
+98 34 3272 4821
Email
drhalehtajadini@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abas Pardakhti
Street address
Ebn-e-Sina St, Jahad Blvd, Kernan
City
Kernan
Province
Kerman
Postal code
7619813159
Phone
+98 34 3226 3719
Fax
+98 34 3226 3857
Email
drhalehtajadini@gmail.com
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
Street address
No9, 19 Jahad Blvd, Kerman
City
Kerman
Province
Kerman
Postal code
7619837773
Phone
+98 34 3243 5539
Email
drhalehtajadini@gmail.com

Person responsible for scientific 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
Street address
No 9, 19 Jahad Blvd, Kerman
City
Kerman
Province
Kerman
Postal code
7619837773
Phone
9832435539
Email
drhalehtajadini@gmail.com

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
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
No. 9, 19 Jahad Blvd., Kerman
City
Kerman
Province
Kerman
Postal code
7619837773
Phone
9832435539
Email
drhalehtajadini@gmail.com

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