Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

A prospective randomized controlled trial comparing the effectiveness of traditional medicine combination based on the Ferula assa-foetida gum - Tragacanth with moderate to severe Coronavirus disease (COVID-19) compared to standard treatment

Protocol summary

Study aim
To evaluate whether traditional medicine combination(the Ferula assa-foetida gum - Tragacanth) increases significant clinical improvement as compared to the standard of treatments in hospitalized patients with moderate to severe COVID-19.

Design
This is a parallel 2-arm randomized, controlled, double-blind, multi center study. 122 patients are enrolled and followed for 14 days.

Settings and conduct
The study will be conducted in Emam Reza hospital (Mashhad), Radiologists, physicians who assess outcomes and the statistician analyzing the data will be blinded but the patients and physicians who treat patients will know the assigned treatment group.

Participants/Inclusion and exclusion criteria
All moderate to severe COVID-19 infected patients admitted to Ema Reza hospital (Mashhad). Inclusion criteria: PCR confirmed; diagnostic chest CT scan.age 18-75y; hospitalization. Exclusion criteria: Patients with end-stage heart failure; Recent cardiac intervention (less than 2 months): (coronary angioplasty, ICD, CABG, Valvuloplasty or replacement); Pulmonary fibrosis or advanced COPD; End-stage kidney or liver disease; Pregnant or lactating ladies; Patients on immunosuppressive therapy; Active tuberculosis; Active hepatitis, Critical stage of COVID

Intervention groups
122eligible patients with moderate to severe COVID-19 in a 1:1 ratio: • Combination of traditional medicine+standard treatment &Control group: standard treatment

Main outcome variables
paraclinical recovery within 14 days from initiation of study the change in peripheral blood lymphocyte count (LC) and the different degrees of blood oxygen saturation (PO2)

General information

Reason for update
Changes in drug composition and outcomes

Acronym

IRCT registration information
IRCT registration number: **IRCT20200607047675N1**
Registration date: **2020-06-15, 1399/03/26**
Registration timing: **prospective**

Last update: **2022-02-25, 1400/12/06**
Update count: **1**

Registration date
2020-06-15, 1399/03/26

Registrant information

Name
Nayereh Esmaeilzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3841 5001

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esmaeilzadehn1@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-19, 1399/03/30

Expected recruitment end date
2020-09-05, 1399/06/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A prospective randomized controlled trial comparing the effectiveness of traditional medicine combination based on the Ferula assa-foetida gum - Tragacanth with moderate to severe Coronavirus disease (COVID-19) compared to standard treatment

Public title
Evaluation of the effectiveness of traditional medicine combination based on the Ferula assa-foetida gum - Tragacanth in Participants with Moderate to Severe Coronavirus Disease (COVID-19)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
PCR confirmed diagnostic chest CT scan Consent for voluntary participation Hospitalization
Exclusion criteria:
Patients with end stage heart failure Recent cardiac intervention (less than 2 months): coronary angioplasty, ICD, CABG, Valvuloplasty or replacement Pulmonary fibrosis or advanced COPD End stage kidney or liver disease Pregnant or lactating ladies Patients on immunosuppressive therapy Active tuberculosis Active hepatitis The critical stage of COID19
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **122**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomized in a 1:1 ratio into one of the traditional treatment and standard treatment using the SPSS randomization plan. The date and time of randomization will be recorded. Allocation concealment will be done with the sealed envelope method.
Blinding (investigator's opinion)
Single 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 Mashhad University of Medical Sciences
Street address
Qurashi Building, University Street
City
Mashad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2020-06-06, 1399/03/17
Ethics committee reference number
IR.MUMS.REC.1399.285

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19

Primary outcomes

1

Description
oxygen saturation (≥94% on room air)
Timepoint
Day 1 and 14
Method of measurement
pulse oximetry

2

Description
Lymphocyte count
Timepoint
Day 1 and 14
Method of measurement
Complete Blood Count

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 300mg of soft Ferula gum and 150mg of soft tragacanth gum: twice a day, and the national guidelines for the treatment of COVID-19
Category
Treatment - Drugs

2

Description
Control group: the national guidelines for the treatment of COVID-19
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
Dr. Amin Bojdy
Street address
Imam Reza Hospital Square
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9137913316
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Majid Ghayour-Mobarhan
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Ghorashi Building, University Street
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Nayereh Esmaeilzadeh
Position
Consultant
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
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Person responsible for scientific inquiries

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Associate professor
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Specialist

Other areas of specialty/work

PhD in Clinical Chinese Medicine

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr. Majid Jafarinejad

Position

Specialist

Latest degree

Specialist

Other areas of specialty/work

Traditional 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

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

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The study protocol, statistical analytic plan informed consent forms will be shared as supplementary material at the time of publication of results.

When the data will become available and for how long

At the time of publication

To whom data/document is available

Will be publically available as a supplement accompanying the published article.

Under which criteria data/document could be used

To interpret the findings of the published study, and to use as a reference for future research

From where data/document is obtainable

On the website of the journal that will publish the research

What processes are involved for a request to access data/document

They will be publically available.

Comments