Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of edible herbal medicine (containing Colchicum autumnale, Olea Europaea, Nigella sativa, Lavandula angustifolia, Zingiber officinale) in decreasing mortality and hospitalization duration in a severe and critical phase of patients with COVID-19.

Protocol summary

Study aim

Determining and comparing the effect of studied herbal medicine in decreasing mortality and hospitalization of patients with COVID-19.

Design

A randomized open-label (without-blinding) clinical trial, with the parallel groups on 150 pateints

Settings and conduct

This randomized open-label clinical trial study was performed on 150 eligible patients with QUID-19, referring to Amin and Al-Zahra hospitals in Isfahan and were randomly divided into 2 groups. The first group receives herbal capsules in addition to the standard treatment and the second group receives only the standard treatment. Then, at the end of the intervention the mortality, and hemodynamic parameters of patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include the age range of 40-80 years, weighing more than 50 kg, definitive infection with Covid 19, being in the acute and critical phase of the disease, and consent to participate in the study. Exclusion criteria included pregnancy, breastfeeding, the existence of active ulcers in the gastrointestinal tract, taking digoxin, admission to the ward before the start of the study, and a history of allergies to medicinal plants.

Intervention groups

Intervention group: Patients in this group receive standard treatment. In addition, they will be prescribed 2 one-gram oral capsules every 8 hours. The capsules contain 500 mg of honey and 500 mg of oily extract of the studied plant compounds in equal proportions.
Control group: Patients in this group will receive only standard treatments.

Main outcome variables

Need for mechanical ventilation; Duration of hospitalization; Need to be admitted to the intensive care unit; death; Number of breaths; heart rate; Interleukin 6; Percentage of oxygen saturation; Lymphocyte level, platelet level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N49**
Registration date: **2021-12-25, 1400/10/04**
Registration timing: **prospective**

Last update: **2021-12-25, 1400/10/04**
Update count: **0**

Registration date

2021-12-25, 1400/10/04

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

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asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of edible herbal medicine (containing Colchicum autumnale, Olea Europaea, Nigella sativa, Lavandula angustifolia, Zingiber officinale) in decreasing mortality and hospitalization duration in a severe and critical phase of patients with COVID-19.

Public title

Evaluation of the effect of edible herbal medicine in decreasing mortality and hospitalization of patients with COVID-19.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 80-40 years Weight over 50 kg Definite infection with COVID-19 according to diagnostic criteria The acute and critical phase of COVID-19 disease who are admitted to the infectious diseases and intensive care unit. Satisfaction to participate in the study

Exclusion criteria:

Pregnancy Breastfeeding Existence of active ulcers in the gastrointestinal tract Patients taking digoxin Patients who have been hospitalized before the start of the study History of allergies to medicinal plants

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

150 eligible patients will be randomly selected. These people are then coded with the help of random allocation computer software and are automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be assigned to a patient and that patient will be randomly studied in one of the two groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfehan

Postal code

8179964167

Approval date

2021-09-28, 1400/07/06

Ethics committee reference number

IR.MUI.MED.REC.1400.514

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Need for mechanical ventilation

Timepoint

After the intervention

Method of measurement

Observational

2

Description

Duration of hospitalization

Timepoint

After the intervention

Method of measurement

Calculate the number of days

3

Description

Need to be admitted to the intensive care unit

Timepoint

After the intervention
Method of measurement
Observational

4

Description
Mortality
Timepoint
After the intervention
Method of measurement
Observational

Secondary outcomes

1

Description
Number of breaths
Timepoint
Before and after the intervention
Method of measurement
Ventilator device

2

Description
Heart rate
Timepoint
Before and after the intervention
Method of measurement
Ventilator device

3

Description
Percentage of oxygen saturation
Timepoint
Before and after the intervention
Method of measurement
Ventilator device

4

Description
Interleukin 6
Timepoint
Before and after the intervention
Method of measurement
Blood test

5

Description
Lymphocyte level
Timepoint
Before and after the intervention
Method of measurement
Blood test

6

Description
Platelet level
Timepoint
Before and after the intervention
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: Patients in this group receive standard treatment. In addition, they will be prescribed 2 one-gram oral capsules every 8 hours. The capsules contain 500 mg of honey and 500 mg of oily extract of the plant compounds (including containing Colchicum autumnale, Olea Europaea, Nigella sativa, Lavandula angustifolia, Zingiber officinale) in equal proportions.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group will receive only standard treatments (including oxygen therapy, antiviral drugs, corticosteroids, anticoagulants and, if necessary, tocilizumab).
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Reza Ghadiri
Street address
Soffe Blvd, Isfahan
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2

Recruitment center
Name of recruitment center
Amin Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash Dastjerdi
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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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8174673461
Phone
+98 31 3668 8597
Email
dean@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
Esfahan University of Medical Sciences
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Position
Non-faculty physician
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available