# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Jun 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)

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**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

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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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Sanbolistan Alley, Ibn Sina Street

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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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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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Reza Ghadiri
**Position**
Non-faculty physician
**Latest degree**
Medical doctor
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## Person responsible for updating data

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**Email**

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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