# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

28 Sep 2026

## The effect of herbal tea (including mallow flower, chicory seeds, sweet violet flower, Melilotus officinalis and Bindii) on improving respiratory symptoms in patients with Covid-19

## Protocol summary

**Study aim**

Determining the effect of herbal tea (including mallow flower, chicory seeds, sweet violet flower, Melilotus officinalis and Bindii) on improving respiratory symptoms in patients with Covid-19

**Design**

A clinical trial, with the parallel groups, no blinding, randomized

**Settings and conduct**

This not blind, randomized clinical trial will be performed at shafa hospital. This study will be performed on 40 patients with Covid-19 in two groups. One group is treated with hydroxychloroquine. The other group will receive herbal tea in addition to hydroxychloroquine treatment.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Positive result of PCR or CT scan for COVID-19 disease in accordance with international standards Age 60-15 years Patient consent to participate in the study exclusion criteria: Has diseases such as Alzheimer's, Parkinson's, multiple sclerosis, neuromuscular diseases, myasthenia gravis Pregnant women Patients with blood pressure lower than 40/90 mmHg Breathe more or equal to 30 per minute Blood oxygen saturation less than 93% at rest PaO2 to FiO2 ratio less than or equal to 300 mmHg Patients with more than 50% of exudative lesions in 24-48 hours in the lung image

**Intervention groups**

Control group: Patients in this group will receive only the routine treatment. Intervention group: Patients in this group, in addition to receiving routine treatment, will use the herbal tea including mallow flower, chicory seeds, sweet violet flower, Melilotus officinalis and Bindii. In this way, a jam spoon (equivalent to 5 grams of powdered this herbal composition) with a cup of boiling water (equivalent to 150 cc) is brewed for 25-30 minutes and after straining it is given to the patient. This herbal tea will be prescribed half an hour after lunch for 5 days.

**Main outcome variables**

Early signs; Clinical manifestations; Patient outcome

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20200806048318N1**
Registration date: **2020-08-20, 1399/05/30**
Registration timing: **prospective**

Last update: **2020-08-20, 1399/05/30**
Update count: **0**

**Registration date**

2020-08-20, 1399/05/30

**Registrant information**

**Name**

Zohreh Vakili

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-09-22, 1399/07/01

**Expected recruitment end date**

2020-12-21, 1399/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of herbal tea (including mallow flower, chicory seeds, sweet violet flower, Melilotus officinalis and Bindii) on improving respiratory symptoms in patients with Covid-19

**Public title**

The effect of herbal tea on improving respiratory symptoms in patients with Covid-19

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Positive result of PCR or CT SCAN of COVID-19 disease in accordance with international standards Age 60-15 years Patient consent to participate in the study

**Exclusion criteria:**

Has diseases such as Alzheimer's, Parkinson's, multiple sclerosis, neuromuscular diseases, myasthenia gravis Pregnant women Patients with blood pressure lower than 40/90 mmHg Breathe more or equal to 30 per minute Blood oxygen saturation less than 93% at rest PaO2 to FiO2 ratio less than or equal to 300 mmHg Patients with more than 50% of exudative lesions in 24-48 hours in the lung image

**Age**

From **15 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be divided into two groups of 40 using the random block method with 2 blocks. So that the first two cases are separated and assigned to group one, the second two cases are separated and assigned to group two, and this will be continued two by two in the same way till the ending of samples.

**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**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezar Jerib street

**City**

Isfahan

**Province**

Isfehan

**Postal code**

8174673461

**Approval date**

2020-08-02, 1399/05/12

**Ethics committee reference number**

IR.MUI.MED.REC.1399.359

## Health conditions studied

### 1

**Description of health condition studied**

COVID-19 disease

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19 disease

## Primary outcomes

### 1

**Description**

Respiratory rate

**Timepoint**

Before the intervention and the first to fifth days of treatment

**Method of measurement**

Observation

### 2

**Description**

Number of coughs

**Timepoint**

Before the intervention and the first to fifth days of treatment

**Method of measurement**

Observation

### 3

**Description**

Percentage of oxygen saturation

**Timepoint**

Before the intervention and the first to fifth days of treatment

**Method of measurement**
Pulse Oximeter device

**4**

**Description**
Shortness of breath
**Timepoint**
Before the intervention and the first to fifth days of treatment
**Method of measurement**
Observation

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Patients in this group, in addition to receiving routine treatment, will use the herbal tea including mallow flower, chicory seeds, sweet violet flower, Melilotus Officinalis, and Bindii. In this way, a jam spoon (equivalent to 5 grams of powdered this herbal composition) with a cup of boiling water (equivalent to 150 cc) is brewed for 25-30 minutes and after straining it is given to the patient. This herbal tea will be prescribed half an hour after lunch for 5 days.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Patients in this group will be received only routine treatment.
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shafa Hospital
**Full name of responsible person**
Mehdi Akhve
**Street address**
Shafa Specialized Hospital (Kalishad and Sudarjan), Baharestan, Kalishad, Isfahan.
**City**
Isfahan
**Province**
Isfehan
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8456168452
**Phone**
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**Email**
--@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Shaghayegh Haghjoo Javanmard
**Street address**
Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
**City**
Isfahan
**Province**
Isfehan
**Postal code**
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
**Full name of responsible person**
Mehdi Akhveh
**Position**
Non-faculty specialist physician
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
**Street address**
Unit 7, First Floor, No. 26, Residence Apartment, Sub-12, West Alley, Telecommunication Street, Shahinshahr.

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## Person responsible for scientific inquiries

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**Latest degree**
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## Person responsible for updating data

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
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**Position**
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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