Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Dec 2023

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)

Phone

+98 31 3331 2755

Email address

z.vakili@resident.mui.ac.ir

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
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8456168452
Phone
+98 31 3748 9392
Fax
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
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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
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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arnica.darou@gmail.com

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Contact
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Full name of responsible person
Mehdi Akhveh
Position
Non-faculty specialist physician
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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arnica.darou@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