Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

The Effect of Persian Medicine Products on the Clinical and Laboratory Symptoms of Patients With or Suspected of Covid-19

Protocol summary

Study aim
Determining the effect of Persian medicine products on O2 saturation in patients with or suspected of COVID-19 Determining the Effect of Persian medicine products on Respiratory Rate in Patients With or Suspected of COVID-19 The effect of Persian medicine products on CRP levels of patients with or suspected of COVID-19 The effect of Persian medicine products on lymphocyte levels in patients with or suspected of COVID-19 Determining the effect of Persian medicine products on WBC levels in patients with or suspected of COVID-19

Design
A randomized clinical trial with two group: control and intervention

Settings and conduct
The study will be conducted at Imam Reza Hospital. Patients will be randomly divided into intervention and control groups. Given the open-label study, Blinding will not happen.

Participants/Inclusion and exclusion criteria
Patients over 18 years old hospitalized with or suspected of COVID-19: Liver, kidney and heart failure, Immunodeficiency, Pregnancy and breast feeding, Hypertension, Alcohol or drug addiction, A history of allergies to medicinal herbs, Patients with transplanted organs, Cor Pulmonel Patients, History of deep vein thrombosis

Intervention groups
Intervention group: standard treatment, Persian medicine capsule, Persian medicine syrup Control group: standard treatment

Main outcome variables
Oxygen saturation: Respiratory Rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140617018126N2**
Registration date: **2020-03-29, 1399/01/10**
Registration timing: **prospective**

Last update: **2020-03-29, 1399/01/10**
Update count: **0**

Registration date
2020-03-29, 1399/01/10

Registrant information

Name
Mostafa Araj-Khodaei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-03, 1399/01/15

Expected recruitment end date
2020-04-18, 1399/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Persian Medicine Products on the Clinical and Laboratory Symptoms of Patients With or Suspected of Covid-19

Public title

Persian Medicine Products in Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Over 18 years old patients hospitalized, with or suspected of COVID-19

Exclusion criteria:

Having liver, kidney and heart failure History of immunodeficiency Breastfeeding and pregnancy Hypertension Alcohol or drug addiction A history of allergies to medicinal herbs Patients with transplanted organs Cor Pulmonale Patients History of deep vein thrombosis

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly assigned to four blocks using Random Allocation Software. Blocking and allocation sequences for concealment will be done by the non-involved researcher (Allocation Concealment).The sample allocation ratio will be Allocation 1:1 and will be divided into two groups of receiving Iranian medicine products and control group (Assignment). Then based on blocks and allocation sequences medication will be given to patients. This is an open-label study and blinding will not happen.

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 Tabriz University of Medical Sciences

Street address

Research Vice Chancellor, Third Floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

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East Azarbaijan

Postal code

5166614766

Approval date

2020-03-16, 1398/12/26

Ethics committee reference number

IR.TBZMED.REC.1398.1318

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

RA01.0

ICD-10 code description

Covid-19

Primary outcomes

1

Description

Oxygen saturation

Timepoint

Clinical examination and Pulse Oximetry before starting medication and regularly during treatment

Method of measurement

Pulse Oximeter

2

Description

Respiratory Rate

Timepoint

Clinical examination before starting medication and regularly during treatment

Method of measurement

respiratory Count

Secondary outcomes

1

Description

C-reactive protein

Timepoint

Intravenous blood testing before starting medication and during treatment

Method of measurement

Intravenous blood test

2

Description

Lymphocytes

Timepoint

Intravenous blood testing before starting medication and

during treatment

Method of measurement

Intravenous blood test

3

Description

White Blood Cells

Timepoint

Intravenous blood testing before starting medication and during treatment

Method of measurement

Intravenous blood test

Intervention groups

1

Description

Intervention group: In the intervention group, in addition to the standard treatment, medicinal herbal products will be prescribed. The drug will be given in two combination forms. One in the form of a syrup containing the following medicinal herbs: Zattaria multiflora, Punicagranatum, Marticaria chamomilla, Zizyphus sativa and Mentha spp, and the other in the form of a capsule containing the following medicinal herbs: Rheum officinale, nigella Sativa andnepeta bracteata . In addition to the usual treatment, the intervention group, will receive a capsule every 8 hours and 10 cc of of Iranian medicine syrup every 8 hours for one week. The capsule will be taken at least half an hour after taking the syrup.

Category

Treatment - Drugs

2

Description

Control group: Get standard treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam reza hospital

Full name of responsible person

Hojjat Pourfathi Nematabad

Street address

Imam Reza Hospital, Opposite the Central Organization of the Tabriz University of Medical Sciences, Golgasht Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Hojjat Pourfathi Nematabad

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Latest degree
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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
No more 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