Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Persian Medicine Formula (Padzahr) on clinical manifestations of patients with COVID-19

Protocol summary

Study aim
The effect of Persian Medicine Formula (Padzahr) on clinical manifestations of patients with COVID-19
Design
68 patients between the ages of 18 and 75 with a probable diagnosis of COVID-19 according to the national protocol, after applying the inclusion and exclusion criteria of the study and completing the conscious consent form with block randomization are placed in one of the intervention and control groups.
Settings and conduct
This study is a type of clinical trial that is not blind and patients who refer to Razi Hospital in Ghaemshahr are diagnosed with COVID-19 manifestation will entered. Then, 68 patients between the ages of 18 and 75 with a probable diagnosis of COVID-19 according to the national protocol, after applying the inclusion and exclusion criteria of the study and completing the conscious consent form with block randomization are placed in one of the intervention and control groups.
Participants/Inclusion and exclusion criteria
Patients between 18 and 75 years with Probable diagnosis of COVID-19 based on national Iranian protocol
Intervention groups
Intervention group: Corona standard treatment + 2 Padzahr tables: after a meal (three times a day). Control group: Corona standard treatment according to the national protocol of the Ministry of Health of Iran.
Main outcome variables
length of hospital stay

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20131129015584N4**
Registration date: **2021-04-04, 1400/01/15**
Registration timing: **prospective**
Last update: **2021-04-04, 1400/01/15**
Update count: **0**
Registration date
2021-04-04, 1400/01/15

Registrant information
Name
Assie Jokar
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-21, 1400/02/01
Expected recruitment end date
2021-12-22, 1400/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Persian Medicine Formula (Padzahr) on clinical manifestations of patients with COVID-19

Public title
The effect of Padzahr tablets on the symptoms of COVID-19
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:

Probable diagnosis of COVID-19 based on national Iranian protocol

Exclusion criteria:

Late 5 days from the onset of symptoms Existence of comorbidity Pregnancy and lactation history of Allergy Complicated with bacterial infection

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Before entering the intervention, each patient selected one of the 68 envelopes containing the codes 0001 to 0068, which was already randomly determined for each code using the Block randomization statistical software output table for each intervention group. Or assigned control. The participants will be assigned to the intervention groups in 17 blocks of 4 in a ratio of one to one (1: 1 Allocation) in order of allocation.

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 Mazandaran University of Medical Sciences

Street address

Moallem square

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Approval date

2021-02-24, 1399/12/06

Ethics committee reference number

IR.MAZUMS.REC.1399.967

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Fever reduction time

Timepoint

Time to start reducing fever after the intervention

Method of measurement

hour

2

Description

Fever intensity

Timepoint

All days of hospitalization

Method of measurement

C

3

Description

Blood oxygen saturation

Timepoint

All days after the intervention

Method of measurement

Pulse oximetry

Secondary outcomes

1

Description

Duration of hospital stay

Timepoint

Patient discharge time

Method of measurement

day

Intervention groups

1

Description

Intervention group: Corona treatment (1- Remedicivir: 200 mg on the first day and then 100 mg daily for 4 days; 2- Dexamethasone: 8 mg daily; 3- Enoxaparin 40 mg every 12 hours or Heparin 5000 units every 8 hours) + Padzahr tablets (made by NIAK with license number 0385-94-S): 2 pieces, after meals (three times a day).

Category
Treatment - Drugs

2

Description
Control group: Corona treatment (1- Remedicivir: 200 mg on the first day and then 100 mg daily for 4 days; 2- Dexamethasone: 8 mg daily; 3- Enoxaparin 40 mg every 12 hours or Heparin 5000 units every 8 hours)
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Alireza Davoudi
Street address
Yousofreza st.
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Ghaemshahr
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۴۵۶۵۶۸۶۱۴۳
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razihospital@mazums.ac.ir
Web page address
https://razihospital.mazums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Majid Saidi
Street address
Moallem squre
City
Sari
Province
Mazandaran
Postal code
۴۸۱۵۷۳۳۹۷۱
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Web page address
https://pajooheshi.mazums.ac.ir/page-NPajooheshiMain/fa/2/form/pId47946
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sciences
Proportion provided by this source
60
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
Mazandaran University of Medical Sciences
Full name of responsible person
Assie Jokar
Position
Associate professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not 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
Yes - There is 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

Title and more details about the data/document
After the publication of the article, the results and how to perform the intervention will be shared

When the data will become available and for how long
After the publication of the article

To whom data/document is available
All academic people

Under which criteria data/document could be used
After the publication of the article and for other studies and therapeutic use

From where data/document is obtainable
The person responsible for scientific accountability

What processes are involved for a request to access data/document
Communication with the person responsible for scientific accountability

Comments