Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of herbal products of Iranian traditional medicine (Ziziphus jujuba, Glycyrrhiza glabra, and Cydonia oblonga) on the symptoms of patients with COVID-19

Protocol summary

Study aim

Determining the effect of herbal products of Iranian traditional medicine (Ziziphus jujuba, Glycyrrhiza glabra, and Cydonia oblonga) on the symptoms of patients with COVID-19

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 will be conducted on 146 patients. Sampling will be block randomization.

Settings and conduct

Eligible patients with covid-19 are selected from Masih Deneshvari in Tehran, Razi in ghaemshahr, shahid beheshti in Kashan and Nekoui, Hedayati, Forghani in Qom Hospitals. Hospitals and randomly divided into two groups. The pharmacist's colleague fills the contents of the bottle with the desired drugs (syrup and placebo) therefore, all collaborators will be blind. Placebo syrup will be used for the control group. However, for the intervention group, syrup made from Ziziphus jujube, Glycyrrhiza glabra, and Cydonia oblonga was administered orally in a daily dose of 32 grams in two divided doses, and then the results were compared in the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having an age between 18 and 75 years and a definite diagnosis of the disease of Covid-19 based on the PCR test or lung CT scan. exclusion criteria: Pregnancy and breastfeeding, History of any allergy to product components, Patient's hypercapnia, Loss of consciousness

Intervention groups

Intervention group: For these patients, the syrup made from Ziziphus jujube, Glycyrrhiza glabra, and Cydonia oblonga is prescribed orally in a daily dose of 32 grams (equivalent to 27 ml) in two divided doses every 12 hours. Control group: A placebo with the same color and consistency is prepared for these patients and administered orally in the same way as the intervention group, i.e. in two divided doses daily.

Main outcome variables

Arterial oxygen saturation, dyspnea severity, duration of dyspnea, fever severity, duration of fever

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211218053445N1**
Registration date: **2022-07-19, 1401/04/28**
Registration timing: **prospective**

Last update: **2022-07-19, 1401/04/28**
Update count: **0**

Registration date

2022-07-19, 1401/04/28

Registrant information

Name

Mohammad Hossin Manian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-22, 1401/04/31

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of herbal products of Iranian traditional medicine (Ziziphus jujuba, Glycyrrhiza glabra, and Cydonia oblonga) on the symptoms of patients with COVID-19

Public title
The effect of herbal products of Iranian traditional medicine (Ziziphus jujuba, Glycyrrhiza glabra, and Cydonia oblonga) on the symptoms of patients with COVID-19
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Being between 18 and 75 years old Definite diagnosis of Covid-19 disease based on PCR test or lung CT scan
Exclusion criteria:
Pregnancy and breastfeeding History of any allergy to product components Patient's hypercapnia Loss of consciousness
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **146**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method will initially be available; Then the samples will be placed in blocks of ten by random block sampling method. The blockage is usually used to balance the number of samples allocated to each of the studied groups. This feature helps researchers to equalize the number of samples allocated to each of the studied groups in cases where intermediate analyzes are required during the sampling process. All blocks are the same size, and in this two-group experiment, we will have 4 blocks (including 2 participants in the intervention group and 2 participants in the control group). Random allocation software is also used to randomize random sequence production software (Random allocation software). To conceal, we use Allocation concealment, which refers to the method used to perform a random sequence on study participants, so that the assigned group is not identified before the individual is assigned. Use non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
The pharmacist's colleague, who does not have access to the subjects, fills the contents of the bottle with the desired drugs (syrup and placebo) according to the sequence he has. He knows which drug group each number belongs to. Subjects receive the envelope and go to the medicine delivery official and according to their envelope number, they will receive a box that matches the same number. Therefore, except for the pharmacist, all project collaborators will be blind to the content of what the subjects receive.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical Sciences
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Babol University of Medical Sciences, Ganj Afrooz St, Babol, Mazandaran
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Postal code
4717647745
Approval date
2022-05-29, 1401/03/08
Ethics committee reference number
IR.MUBABOL.HRI.REC.1401.076

Health conditions studied

1

Description of health condition studied
COVID-19 disease
ICD-10 code
B34.2

ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Fever duration
Timepoint
After the intervention
Method of measurement
Thermometer(length of days the patient has a fever)

2

Description
Fever severity
Timepoint
After the intervention
Method of measurement
Thermometer

3

Description
Arterial oxygen saturation
Timepoint
After the intervention
Method of measurement
pulse oximeter

4

Description
Cough severity
Timepoint
After the intervention
Method of measurement
Cough Severity Index (CSI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For these patients, the syrup made from Ziziphus jujube, Glycyrrhiza glabra, and Cydonia oblonga is prescribed orally in a daily dose of 32 grams (equivalent to 27 ml) in two divided doses every 12 hours.
Category
Treatment - Drugs

2

Description
Control group: A placebo product with the same color and consistency is prepared for these patients. In order to homogenize the smell, the extract is added in the amount of 1%. Carboxymethyl cellulose (CMC) (0.5-1%) is used in order to achieve the appropriate viscosity for the placebo formulation. Sodium benzoate and potassium sorbate (0.3 and 0.2%, respectively) are added to the mixture as microbial preservatives and administered orally in the same way as the intervention group, i.e. in two divided doses every 12 hours.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Mohammad Hosein Manian
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Recruitment center
Name of recruitment center
Nekuei Hedayati Forqani Hospital
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Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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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
Babol 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
Babol University of Medical Sciences
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Position
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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)
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