Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparison of Elderberry (Sambucus nigra) extract syrup and placebo against COVID-19 symptoms in outpatients and home quarantined patients: A randomized double-blind clinical trial

Protocol summary

Study aim
Clinical trial of the effects of elderberry extract syrup against COVID-19 symptoms in outpatients and home quarantined patients

Design
This is a randomized, double-blinded, placebo controlled clinical trial with a parallel group design of 40 patients. Randomization will be performed with the table of random numbers.

Settings and conduct
This study will be performed on outpatients and home quarantined patients. 40 patients with COVID-19 disease will be selected and randomly assigned to two groups of 20 individuals (Imam Reza hospital, Mashhad, Razavi Khorasan). Then the clinical symptoms and laboratory results of the patients will be monitored on days 3, 7 and 14 from the beginning of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People over 18 years and under 65 years old with a diagnosis of coronavirus infection based on clinical symptoms and laboratory results; home quarantined patients and outpatients. Non-inclusion criteria: Patients receiving chemotherapy drugs, diabetics, patients with gastrointestinal and respiratory diseases.

Intervention groups
The control group receives standard anti-coronavirus drugs with placebo. The intervention group receives standard anti-coronavirus drugs with elderberry syrup.

Main outcome variables
Lymphocytopenia and clinical symptoms including fever, coughs and myalgia; CRP

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200406046965N1**
Registration date: **2020-04-12, 1399/01/24**
Registration timing: **prospective**

Last update: **2020-04-12, 1399/01/24**
Update count: **0**

Registration date
2020-04-12, 1399/01/24

Registrant information

Name
Seyed Ahmad Emami

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3180 1267

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emamia@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-20, 1399/02/01

Expected recruitment end date
2020-07-22, 1399/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparison of Elderberry (Sambucus nigra) extract syrup and placebo against COVID-19 symptoms in

outpatients and home quarantined patients: A randomized double-blind clinical trial

Public title
The effect of elderberry syrup against COVID-19 symptoms
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A definitive diagnosis of COVID-19 infection based on laboratory confirmation (lymphocytopenia, increased quantitative CRP, chest X-ray results) and clinical symptoms of patients including fever, coughs and myalgia Outpatients and home quarantined patients
Exclusion criteria:
Hospitalization Age> 65 y and <18 y Patients with catheter Patients receiving chemotherapy drugs, corticosteroids and theophylline Autoimmunity Gastrointestinal diseases Migraine Diabetes Hypokalemia Myalgia Respiratory diseases Smoking Pregnancy and breast feeding
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization happens at three stages: 1- Random sequence generation: Simple or limited randomization will be performed based on the table of random numbers. 2- Allocation concealment: This step will be performed in the form of coded boxes (numbered drug containers) with a random sequence. In this method, a number of boxes with the same shape and size are numbered based on random sequences, containing either treatment drug or placebo with a completely similar appearance. 3- Execution of random allocation process: A: To identify the person who creates the random sequence B: A person who evaluates and registers researchers in terms of inclusion and exclusion criteria. C: The person who has assigned the participants to the groups: Infectious diseases specialist who creates a random sequence, does not interfere in other stages of randomization, including registration and allocation of participants. The person involved in creating a random program is separate from other researchers.
Blinding (investigator's opinion)
Double blinded
Blinding description
The treatment drug and placebo are given as same-colored syrups with same-sized containers in boxes labeled with the letters A and B. The medical staff, the patient and the data collector are unaware of the nature of the drug or placebo and of the content of the boxes. The executor of this research project is the only person aware of the contents of boxes.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Medical Ethics Committee of Mashhad University of Medical Sciences
Street address
School of Pharmacy, University Campus, Vakil Abad boulvard
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948954
Approval date
2020-04-06, 1399/01/18
Ethics committee reference number
IR.MUMS.REC.1399.045

Health conditions studied

1

Description of health condition studied
COVID-19 disease
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Fever
Timepoint
Days 3, 7 and 14 after the intervention beginning
Method of measurement
Thermometer

2

Description
Shortness of breath
Timepoint
Days 3, 7 and 14 after the intervention beginning
Method of measurement
Autosaturation device, Counting the number of breaths in 1 minute

3

Description
Coughs
Timepoint
Days 3, 7 and 14 after the intervention beginning
Method of measurement
Patient follow up

4

Description
Myalgia
Timepoint
Days 3, 7 and 14 after the intervention beginning
Method of measurement
Patient follow up

Secondary outcomes

1

Description
Lymphocytopenia
Timepoint
days 3, 7 and 14 after the intervention beginning
Method of measurement
Cell counter

2

Description
C-reactive protein
Timepoint
days 3, 7 and 14 after the intervention beginning
Method of measurement
CRP kit

Intervention groups

1

Description
Intervention group:The patients will receive 10 ml of elderberry extract syrup 3 times daily (2.6 g of elderberry extract per day equivalent to 15.76 g of fresh elderberries) beside the standard treatment regimen for COVID-19 according to the Ministry of Health protocol. This treatment will continue for 2 weeks. The syrup is formulated according to the United States Pharmacopoeia description. This syrup is preservative-free and remains stable for up to 1 month. The syrups will be prepared freshly at the School of Pharmacy, Mashhad University of Medical Sciences.
Category
Treatment - Drugs

2

Description
Control group: The patients will receive the placebo syrup beside the standard treatment regimen for COVID-19 according to the Ministry of Health protocol with the same order as the intervention group.The placebo consists of USP syrup formula with food-grade coloring agents with the same shape and size containers as the elderberry syrup. This syrup is preservative-free and will be prepared freshly at the School of Pharmacy, Mashhad University of Medical Sciences.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Mohammad Javad Dehghan Nayyeri
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Imam Reza Square, Ebne-sina Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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Ghoreshi Building, Daneshgah street
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Seyed Ahmad Emami
Position
Professor
Latest degree
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Other areas of specialty/work
Medical Pharmacy
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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
Not applicable