

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 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)

Phone

+98 51 3180 1267

Email address

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		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.	
Public title	The effect of elderberry syrup against COVID-19 symptoms	Placebo	Used
Purpose	Treatment	Assignment	Parallel
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	Other design features	
Age	From 18 years old to 65 years old	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	2	1	
Groups that have been masked	- Participant - Care provider - Outcome assessor - Data analyser - Data and Safety Monitoring Board	Ethics committee	
Sample size	Target sample size: 40	Name of ethics committee	Medical Ethics Committee of Mashhad University of Medical Sciences
Randomization (investigator's opinion)	Randomized	Street address	School of Pharmacy, University Campus, Vakil Abad boulevard
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.	City	Mashhad
Blinding (investigator's opinion)	Double blinded	Province	Razavi Khorasan
Blinding description		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

Street address

Imam Reza Square, Ebne-sina Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

dehghanmj@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Ghoreshi Building, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

tafaghodim@mums.ac.ir

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
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
School of Pharmacy, University Campus, VakilAbad
boulevard
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948954
Phone
+98 51 3180 1267
Email
emamia@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Seyed Ahmad Emami
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address

School of Pharmacy, University Campus, VakilAbad
boulevard
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948954
Phone
+98 51 3180 1267
Email
emamia@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Seyed Ahmad Emami
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
School of Pharmacy, University Campus, VakilAbad
boulevard
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948954
Phone
+98 51 3180 1267
Email
emamia@mums.ac.ir

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