

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluating the effect of Terminalia chebula, Pistacia lenticus and brown sugar oral preparation on respiratory clinical findings and inflammatory indicators in patients with COVID-19

Protocol summary

Study aim

Determining the effect of T.chebula, P.lenticus and brown sugar on clinical respiratory findings and inflammatory markers in patients with Covid 19

Design

Clinical trial with control group, with parallel intervention group, double-blind (patient and therapist) and randomized

Settings and conduct

setting of study is Family hospital of army .In this study, 200 newly diagnosed COVID-19 hospitalized patients are selected based on inclusion and exclusion criteria . Patients are divided into two equal groups using the random function of Math lab software. beyond standard treatment based on the protocol recommended by the Ministry of Health for hospitalized patients, intervention and control groups will receive medication and placebo one tablet every 6 hours for 5 days,respectively. The course of symptoms and clinical findings will be monitored daily by the project colleagues and the paraclinical findings will be evaluated before and after the 5-day intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Non-pregnant and non-lactating women and men over 18 years with positive PCR for Covid 19 2. Existence of at least two of the following findings: RR>20, SO₂<93%, GGO>10%, Presence of at least one underlying disease (DM, HTN, HF, COPD, asthma, Immunodeficiency) 3. Informed written consent to participate in the study Exclusion Criteria: 1. History of receiving the Covid 19 vaccine 2. Participation in another clinical trial

Intervention groups

Medication group (n = 100) and placebo group (n = 100)

Main outcome variables

death ratio, need for ICU admission , duration of hospitalization, severity of shortness of breath, cough

intensity, SO₂ changes, RR changes, changes in inflammatory markers (ESR, CRP, LDH, WBC)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210803052060N1**

Registration date: **2021-09-12, 1400/06/21**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-12, 1400/06/21**

Update count: **0**

Registration date

2021-09-12, 1400/06/21

Registrant information

Name

Sajjad Panahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-11, 1400/05/20

Expected recruitment end date

2021-11-11, 1400/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the effect of Terminalia chebula, Pistacia lentiscus and brown sugar oral preparation on respiratory clinical findings and inflammatory indicators in patients with COVID-19

Public title
Effect of Terminalia chebula, Pistacia lentiscus and brown sugar oral combination in covid-19 treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Men and women above 18 years with positive PCR test for Covid-19 At least two of these findings: GGO>10%, SO2<93%, RR>20, at least one underlying disease (COPD, HF, HTN, DM, Asthma, Immunodeficiency)
Conscious written consent to participate in the study
Exclusion criteria:
Covid vaccination history Participation in another clinical trial

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Using MATLAB software version R2018b, 200 people are randomly divided into two groups of 100 intervention (A) and control (B) using randperm(n, k) command. The randperm(n, k) command randomly extracts a non-duplicate number from range 1 to n. Thus, each of the numbers 1 to 200, which represent 200 patients, can be assigned to only one of the groups A or B. There is no specific pattern for assigning to each of the groups, and only by referring to the file extracted from the program command, you can find the assignment of each number to each of groups A or B. Thus, patient number 1 is given a code 1 drug package. The medicine package is filled based on the extracted file by a person who is not involved in the research process.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, according to the use of random number method and similarity of drug and placebo, only by referring to the Excel file of random division can be aware of the presence of the person in the intervention or control group. Access to this file is only possible for

the drug packer who is not present during the project implementation process. Therefore, the patient and all medical staff of the hospital, including the evaluator, are kept blind to the study groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Committees of AJA University of Medical Sciences

Street address

West Fatemi St., Etemad Zadeh St., AJA University of Military Medical Sciences

City

Tehran

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Postal code

1411718541

Approval date

2021-07-03, 1400/04/12

Ethics committee reference number

IR.AJAUMS.REC.1400.083

Health conditions studied

1

Description of health condition studied

new Corona virus disease 2019

ICD-10 code

U07.1

ICD-10 code description

new Corona virus disease 2019

Primary outcomes

1

Description

ICU admission or intubation

Timepoint

During hospitalization, daily

Method of measurement

Evaluator report

Secondary outcomes

1

Description

Clinical symptoms(The degree of shortness of breath, cough intensity)

Timepoint

During hospitalization, daily

Method of measurement

Symptoms by asking the patient as a scale indicator and signs by monitoring the patient by the assessor

2

Description

Inflammatory markers (ESR, CRP, LDH, WBC)

Timepoint

before and after the 5 days intervention

Method of measurement

Quantitative laboratory measurements of blood samples

3

Description

Clinical examinations (RR, SO2)

Timepoint

During hospitalization, daily

Method of measurement

Through clinical examination and use of pulse oximeter

Intervention groups

1

Description

Intervention group: COVID-19 standard treatment based on the protocol recommended by the Ministry of Health for hospitalized patients (remdesivir, prophylactic anticoagulant, and low dose corticosteroids) and tablets obtained from a combination of Terminalia chebula, Pistacia lentiscus, and brown sugar oral preparation, one tablet every 6 hours for 5 days (750 mg tablets prepared in the Department of Pharmacy, AJA University of Medical Sciences)

Category

Treatment - Drugs

2

Description

Control group: COVID-19 standard treatment based on the protocol recommended by the Ministry of Health for hospitalized patients (remdesivir, prophylactic anticoagulant, and low dose corticosteroids) and placebo, one tablet every 6 hours for 5 days (Starch tablets prepared in the Department of Pharmacy, AJA University of Medical Sciences).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khanevadeh Artesh Hospital

Full name of responsible person

Sajjad Panahi

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Kaj St., Shariati Ave., Khanevadeh Artesh Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

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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

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Sajjad Panahi

Position

research fellow

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Nafiseh Hosseini Yekta

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Traditional Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data is shared after deleting personal information

When the data will become available and for how long

Late 2021

To whom data/document is available

Everyone

Under which criteria data/document could be used

Free access

From where data/document is obtainable

responsible author

What processes are involved for a request to access data/document

Request from the responsible author

Comments