Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

Study aim
Determining the effect of T.chebula, P.lentiscus 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 recieve 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 admision , 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

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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 lenticus and brown sugar oral preparation onrespiratory 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

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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 admision 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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Sponsors / Funding sources

1

Sponsor
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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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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 auther

What processes are involved for a request to access data/document
Request from the responsible author

Comments