Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

The study of the effect of herbal drug Phyllanthus Emblica, Rosa Damascene, Althaea Officinalis and Honey in patient with covid 19 referring to Ahvaz Jundishapur university of Medical Science hospitals.

Protocol summary

Study aim

The study of the effect of herbal drug phyllanthus Emblica, Rosa Damascene, Althaea Officinalis and Honey in patient with covid 19 referring to Ahvaz Jundishapur University of Medical Science hospitals.

Design

Randomize double blind clinical trial, with control group, with a sample size of 60 people, with parallel groups, Phase 3 of Clinical trial

Settings and conduct

The place of the study is Ahvaz University of medical science hospitals, simple sampling of patients with random allocation, double blind clinical trial, used drug and placebo, Supervisor and participants are blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age ≥18 years 2. Polymerase chain reaction (PCR) test confirmed infection with COVID 19. 3. Lung involvement in imaging 4. Hospitalized 5. Less than 8 days since illness onset 6. Willingness of study participant to accept randomization to any assigned treatment arm. 7. Must agree not to enroll in another study before 28th day of this study. Exclusion Criteria: 1. Receipt of any another experimental treatment 2. Severe liver disease 3. Known allergic reaction to drugs 4. Severe renal disease 5. Pregnant or breastfeeding women 6. transferred to another hospital

Intervention groups

They receive medicine. 1000 g of amla plant powder soaked in rose water is mixed with 500 g of marshmallow powder, 500 g of rose powder and 5 kg of honey and then packed in 150 g cans. Control group: Placebo will receive 3500 g of starch powder. It mixes well with 3,500 grams of sugar syrup and is packaged in 150-gram cans, and patients take 5 grams of the drug or placebo every 6 hours.

Main outcome variables

virus polymerase reaction, fever,respiratory rate, dyspnea, chill, cough, Body Pain, Weakness, chest CT scan, lymphocyte blood count, neutrophil blood count, platelet, C _ reactive protein, erythrocyte sedimentation rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200404046937N3**
Registration date: **2020-06-25, 1399/04/05**
Registration timing: **prospective**

Last update: **2021-06-02, 1400/03/12**
Update count: **1**

Registration date

2020-06-25, 1399/04/05

Registrant information

Name

Mehran Varnaseri ghandali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 7446

Email address

varnaseri-m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-27, 1399/04/07

Expected recruitment end date

2020-07-28, 1399/05/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the effect of herbal drug Phyllanthus Emblica, Rosa Damascene, Althaea Officinalis and Honey in patient with covid 19 referring to Ahvaz Jundishapur university of Medical Science hospitals.

Public title

Evaluating the effect of Phyllanthus Emblica, Rosa Damascene, Marshmallow and Honey on COVID 19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age ≥18 years Laboratory polymerase chain reaction (PCR) confirmed infection with COVID19 Lung involvement confirmed with chest imaging Hospitalized with: Fever or Respiratory rate >24/min Or Cough Less than 8 days since illness onset Willingness of study participant to accept randomization to any assigned treatment arm Acceptance of non-participation in another study before the 28th day of the study

Exclusion criteria:

Receipt of any experimental treatment for COVID 19 within the 30 days prior to the time of the screening evaluation Severe liver disease Known allergic reaction to drugs Severe renal disease Pregnant or breastfeeding women Transfer to another hospital within the next 72 hours

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two Therapeutic groups by random method and used 6 blocks method. Individuals are the randomization unit and randomization tools are statistical soft ware, make a random sequence is by using statistical soft ware allocation concealment is by assigning unique codes

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind: Supervisor and the participants are blind to the prescription drug of the target group and the control group The drugs of both groups are distinguished in the same form. phyllanthus Emblica, Rosa damascene, Honey and Marshmallow have no significant smell and placebo will be the same color as the medicine by using allowed color. Also there is no significant difference between drug and placebo taste. The package are separated by mentioning the number. The list of numbers will be provided to the statistical consultant and then the data will be analyzed

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical

Street address

Ethics committee, main building, Ahvaz University of medical science, Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6133744151

Approval date

2020-05-29, 1399/03/09

Ethics committee reference number

IR.AJUMS.REC.1399.208

Health conditions studied

1

Description of health condition studied

COVID 19

ICD-10 code

U07.1

ICD-10 code description

Corona virus infection, unspecified

Primary outcomes

1

Description

Viral diagnostic test

Timepoint

The first day of the study and the end of the study

Method of measurement

Polymerase chain reaction

Secondary outcomes

1

Description
Fever
Timepoint
Daily
Method of measurement
Thermometer

2

Description
Chill
Timepoint
Daily
Method of measurement
Patients interview and patient file

3

Description
Respiratory Rate
Timepoint
Daily
Method of measurement
Patients interview and patient file

4

Description
Dyspnea
Timepoint
Daily
Method of measurement
Patients interview and patient file

5

Description
Cough
Timepoint
Daily
Method of measurement
Patients interview and patient file

6

Description
Body Pain
Timepoint
Daily
Method of measurement
Patients interview and patient file

7

Description
Weakness
Timepoint
Daily
Method of measurement
Patients interview and patient file

8

Description
Lymphocyte blood count
Timepoint
The first day of the study and the end of the
Method of measurement
Cell counter

9

Description
C_reactive protein
Timepoint
The first day of the study and the end of the
Method of measurement
Agglutination Kit

10

Description
Erythrocyte sedimentation Rate
Timepoint
The first day of the study and the end of the study
Method of measurement
Wester Green

11

Description
Neutrophyle blood count
Timepoint
The first day of the study and the end of the study
Method of measurement
Cell counter

12

Description
Platelet
Timepoint
The first day of the study and the end of the study
Method of measurement
Cell counter

13

Description
Chest CT Scan
Timepoint
The first day of the study and the end of the study
Method of measurement
CT scan set

Intervention groups

1

Description
Intervention group: Patients in the target group will receive the target group drug after treatment with

routine medications. To prepare the target drug, 1000 g of Amla fruit is soaked in rose water and then ground, then combined with 500 g of rose petal powder, 500 g of marshmallow powder and 5 kg of honey, and the ingredients are carefully mixed together. Stir slowly to form a homogeneous composition and the final product is an oral concoction that is packaged in suitable 150 g storage cans and patients will want 5 g of this drug every 6 hours.

Category

Treatment - Drugs

2

Description

Control group: Patients will be treated with placebo after treatment with routine medications. To prepare a placebo, 3500 g of starch powder with 3500 g of sugar syrup are mixed well and with natural and authorized color, it is completely similar to the main medicine and then it is packed in 150 g packages and patients should take 5 g of medicine every 6 hours.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital, Ahvaz

Full name of responsible person

Mehran Varnaseri Ghandali

Street address

Sina hospital, 5th Gandomkar st, Koot Abdollah Ave

City

Ahvaz

Province

Khouzestan

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6155819953

Phone

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2

Recruitment center

Name of recruitment center

Razi hospital, Ahvaz

Full name of responsible person

Mehran Varnaseri Ghandali

Street address

Razi hospital, Felestin Ave, Amanieh Ave

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6196514941

Phone

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3

Recruitment center

Name of recruitment center

Taleghani hospital, Ahvaz

Full name of responsible person

Mehran Varnaseri Ghandali

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Taleghani hospital, Mostaan Ave, Amanieh Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Main building, Ahvaz University of Medical Science, Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6135539345

Phone

+98 61 3311 3815

Email

Badavi-m@ajums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mehran Varnaseri Ghandali

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehran Varnaseri Ghandali

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehran Varnaseri Ghandali

Position

Assistant professor

Latest degree

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Other areas of specialty/work

Infectious diseases

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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