

# 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  $\geq 18$  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  $\geq$ 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

##### Postal code

6155819953

##### Phone

+98 61 3555 0592

##### Email

drvarnaseri.m@gmail.com

### 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

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6196514941

#### Phone

+98 61 3333 7446

#### Email

drvarnaseri.m@gmail.com

### 3

#### Recruitment center

##### Name of recruitment center

Taleghani hospital, Ahvaz

##### Full name of responsible person

Mehran Varnaseri Ghandali

##### Street address

Taleghani hospital, Mostaan Ave, Amanieh Ave

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6196514988

##### Phone

+98 61 3333 0927

##### Email

drvarnaseri.m@gmail.com

## 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

**Phone**

+98 61 3333 7446

**Email**

drvarnasseri.m@gmail.com

**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

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Razi hospital, Felestin Ave, Amanieh Ave

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**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

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**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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**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6196514941

**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