Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the therapeutic effect of Phyllanthus Emblica on COVID 19 patients, A double blind clinical trial

Protocol summary

Study aim
Evaluating the therapeutic effect of Phyllanthus Emblica e on COVID 19 patients, a double blind clinical trial

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. Physician decision not to participate in the study 2. Severe liver disease 3. Known allergic reaction to Phyllanthus Emblica 4. Severe renal disease 5. Pregnant or breastfeeding women 6. Will be transferred to another hospital 7. Receipt of any another experimental treatment 8. Angiotensin converting enzyme (ACE) inhibitor users

Intervention groups
Main group will be received the drug of the study. Every sacher in main group contains 2 gram of Phyllanthus Emblica powder. Control group will be received placebo. Every sacher in control group contains 2 gram of starch powder. Patients should infuse the contents of one packet with 250 cc of boiling water for 10 minutes every 12 hours, then strain and sip

Main outcome variables
Virus polymerase reaction, fever, dyspnea, chill, cough, Chest X ray, chest CT scan, lymphocyte blood count, C_ reactive protein

General information

Reason for update
Correct typing error

Acronym

IRCT registration information
IRCT registration number: **IRCT20200404046937N2**
Registration date: **2020-04-13, 1399/01/25**
Registration timing: **prospective**

Last update: **2020-08-01, 1399/05/11**
Update count: **3**

Registration date
2020-04-13, 1399/01/25

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
2020-04-13, 1399/01/25

Expected recruitment end date
2020-06-14, 1399/03/25

Actual recruitment start date
2020-05-01, 1399/02/12

Actual recruitment end date
2020-05-22, 1399/03/02

Trial completion date
2020-06-01, 1399/03/12

Scientific title
Evaluating the therapeutic effect of Phyllanthus Emblica on COVID 19 patients, A double blind clinical trial

Public title
Evaluating the effect of Phyllanthus Emblica on COVID 19 patients

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 (axillar or oral temperature ≥ 38.0°) 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:
Physician makes a decision that trial involvement is not in patients' best interest, or any condition that does not allow the protocol to be followed safely. Severe liver disease Known allergic reaction to Phyllanthus Emblica Severe renal impairment Pregnant or breastfeeding women Transfer to another non-study hospital within the next 72 hours Receipt of any experimental treatment for COVID 19 within the 30 days prior to the time of the screening evaluation Angiotensin converting enzyme (ACE) inhibitor user

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Actual sample size reached: **61**

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 software, make a random sequence is by using statistical software. 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 (aluminium package). Phyllanthus Emblica 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 Science

Street address
Ethics committee, main building, Ahvaz University of Medical Science, Golestan

City
Ahvaz

Province
Khouzestan

Postal code
6133744151

Approval date
2020-04-04, 1399/01/16

Ethics committee reference number
IR.AJUMS.REC.1399.011

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 (10th day)

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
Cough
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
Lymphocyte blood count
Timepoint
The first day of the study and the end of the study (10th day)
Method of measurement
Cell counter

6

Description
C_reactive protein
Timepoint
The first day of the study and the end of the study (10th day)
Method of measurement
Agglutination kit

7

Description
Chest CT scan
Timepoint
The first day of the study and the end of the study (10th day)
Method of measurement
CT scan set

Intervention groups

1

Description
Intervention group: After routine treatment, the main group will be received the drug of the study. Drugs are in the sacher form. Every sacher contain 2 gram of Phyllanthus Emblica powder. For 10 days Patients should infuse the contents of one packet with 250 cc of boiling water for 10 minutes every 12 hours, then strain and sip
Category
Treatment - Drugs

2

Description
Control group: After routine treatment, the control group willl be received the placebo. They are in the sacher form. The contents of each package of placebo is 2 grams of starch powder. For 10 days, patients should infuse the contents of one packet with 250 cc of boiling water for 12 minutesevery 12 hours, then strain and sip.
Category
Placebo

Recruitment centers

1

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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Khouzestan
Postal code
6196514941
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Dr.varnaseri@gmail.com

2

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Mehran Varnaseri Ghandali
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Sina hospital, 5th Gandomkar st, Koot Abdollah 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
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
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Person responsible for updating data

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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