Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Oct 2026

Evaluating the therapeutic effect of a mixed herbal drink of Marshmallow and Licorice on COVID 19 patients, A double blind clinical trial

Protocol summary

Study aim
Evaluating the therapeutic effect of a mixed herbal drink of marshmallow and licorice 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. Low oxygen saturation 4. Known allergic reaction to Marshmallow or Licorice 5. Severe renal disease 6. Pregnant or breastfeeding women 7. Will be transferred to another hospital 8. Receipt of any another experimental treatment 9. Angiotensin converting enzyme (ACE) inhibitor users 10. Hypertensive patients

Intervention groups
Main group will be received the drug of the study. Every sacher in main group contains 2.5 gram of Marshmallow and 2.5 gram of Licorice. Control group will be received placebo, Every sacher in control group contains 5 gram of starch. 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: **IRCT20200404046937N1**
Registration date: **2020-04-09, 1399/01/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-18, 1399/01/30**
Update count: **1**

Registration date
2020-04-09, 1399/01/21

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
2020-04-09, 1399/01/21

Expected recruitment end date
2020-06-10, 1399/03/21

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the therapeutic effect of a mixed herbal drink of Marshmallow and Licorice on COVID 19 patients, A double blind clinical trial

Public title

Evaluating the effect of Marshmallow and Licorice 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 °centigrade(C) or ≥38.6°centigrade tympanic or rectal) 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 Oxygen saturation≤94% Known allergic reaction to Marshmallow or Licorice 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 users Hypertensive patients

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**

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(aluminium package). Licorice 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

2020-04-04, 1399/01/16

Ethics committee reference number

IR.AJUMS.REC.1399.012

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

The first day of the study and the end of the study (10th day)

Method of measurement

Thermometer

2

Description

Chill

Timepoint

The first day of the study and the end of the study (10th day)

Method of measurement

Patients interview and patient file

3

Description

Cough

Timepoint

The first day of the study and the end of the study (10th day)

Method of measurement

Patients interview and patient file

4

Description

Dyspnea

Timepoint

The first day of the study and the end of the study (10th day)

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 X ray

Timepoint

The first day of the study and the end of the study (10th day)

Method of measurement

Radiology set

8

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 2.5 gram of Marshmallow and 2.5 gram of Licorice. 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 5 grams of starch powder. For 10 days, patients should infuse the contents of one packet with 250 cc of boiling water for 12 minutes every 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

City
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Province
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Email
Dr.varnaseri@gmail.com

2

Recruitment center
Name of recruitment center
Sina hospital, Ahvaz
Full name of responsible person
Mehran Varnaseri Ghandali
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Email
Dr.varnaseri@gmail.com

3

Recruitment center
Name of recruitment center
Narges Moareffi Mahshahr hospital
Full name of responsible person
Niloofar Mohammad Rezaee Esferjani
Street address
Narges Moareffi hospital, Mottahari Ave
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Postal code
6155634533
Phone
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Email
Niloofarmohamadrezai@yahoo.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
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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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Razi hospital, Felestin Ave, Amanieh Ave
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Person responsible for scientific inquiries

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Position
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Latest degree
Specialist
Other areas of specialty/work
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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