Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Evaluation of the Effect of Herbal Syrup on Clinical Outcome of Inpatient with Moderate to Severe COVID-19 Patient

Protocol summary

Study aim
Study of the effect of hyssop, yarrow, apple, and lonicera herbal syrup on the recovery of patients with COVID-19

Design
Clinical trial with control group, with parallel, randomized, phase 3 groups per 66 patients. Excel software rand function was used for randomization.

Settings and conduct
Patients over18 years of age with moderate to severe severity of covid19 patients admitted to Shohadie-Ashayer hospital in Khorramabad in 2021, eligible for inclusion in the study are randomly divided into two groups of intervention and control and their clinical consequences will be examined.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Hospitalized patients suspected to COVID-19 infection who tested positive for PCR or despite the negative PCR test who have a strong clinical evidence plus typical radiographic sing of COVID-19 that is difficult to justify their symptoms based on other diseases. Exclusion criteria: dissatisfaction with the company; discharge of a patient with a criterion other than recovery; admission to another interventional study; need to be admitted to the intensive care unit; occurrence of side effects such as hypersensitivity reactions; G6PD deficiency; taking antiplatelet drugs; blood pressure medications; sedatives and barbiturates; receiving cardiac glycosides; hepatic-renal problems; Cushing's syndrome; epilepsy.

Intervention groups
Intervention group: receiving 15 cc daily, three times a day orally of herbal syrups (each 100 ml of syrup prepared from 10 grams of apples, 15 grams of lonicera, 15 grams of hyssop and 9 grams of yarrow). Control group: the group receiving placebo syrup that is given daily in two divided doses.

Main outcome variables
Duration of hospitalization; survival rate of 28 days from the time of hospitalization; the duration of recovery or the duration of entry into the disease stage

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200721048159N2**
Registration date: **2021-04-22, 1400/02/02**
Registration timing: **prospective**

Last update: **2021-04-22, 1400/02/02**
Update count: **0**

Registration date
2021-04-22, 1400/02/02

Registrant information

Name
Forouzan Ahmadpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 66 3312 0239

Email address
ahmadpoor.f@lums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-04, 1400/02/14

Expected recruitment end date
2021-09-22, 1400/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the Effect of Herbal Syrup on Clinical Outcome of Inpatient with Moderate to Severe COVID-19 Patient

Public title
The effect of herbal syrup in the treatment of COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Hospitalized patients suspected to COVID-19 infection who tested positive for PCR or despite the negative PCR test who have a strong clinical evidence plus typical radiographic sing of Covid19 that is difficult to justify their symptoms based on other diseases The presence of respiratory symptoms (including shortness of breath, pain and pressure in the chest) with or without fever equal to or greater than 38 degrees Celsius and SpO2 less than 93%.

Exclusion criteria:
Dissatisfaction with the company Discharge of a patient with a criterion other than recovery Admission to another interventional study Need to be admitted to the intensive care unit Occurrence of side effects such as hypersensitivity reactions G6PD deficiency Taking antiplatelet drugs, blood pressure medications, sedatives and barbiturates Receiving cardiac glycosides Hepatic-renal problems Cushing's syndrome Epilepsy

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data and Safety Monitoring Board

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the 4-tier randomized block method is used to randomly assign patients to two groups A ('intervention group') and group B (control group). To do this, first by considering the classes as the age range under 50 years and over 50 years within each class, a list of blocks is written and numbers are assigned to them. (AABB (1) - ABAB (2) -ABBA (3) -BBAA (4) - BABA (5) - BAAB (6)). Then, using a table of random numbers, the numbers between one to 6 (for example, 1,4,5, etc.) are randomly selected, and finally the list of treatment assignments will be formed based on a sequence of letters A and B.

Blinding (investigator's opinion)
Triple blinded

Blinding description
This study is a triple blind and the patient, the treatment evaluator, and the statistician are unaware of the experimental group

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Lorestan University of Medical Sciences

Street address
Office of Research Ethics Committee, Lorestan University of Medical Sciences, 3 km of Khorramabad Road, Tehran

City
Khorramabad

Province
Lorestan

Postal code
381351698

Approval date
2020-12-05, 1399/09/15

Ethics committee reference number
IR.LUMS.REC.1399.240

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Duration of hospitalization

Timepoint
Daily for 5-10 days

Method of measurement
Based on patient file information

Secondary outcomes

1

Description
The duration of recovery or the duration of entry into the disease stage
Timepoint
Daily for 5-10 days
Method of measurement
Based on patient file information

2

Description
Survival rate of 28 days from the time of hospitalization
Timepoint
28 days after starting the study
Method of measurement
Interview with the patient or her family

3

Description
The amount of arterial oxygen saturation
Timepoint
Daily for 5-10 days
Method of measurement
Using a device to measure the percentage of oxygen saturation

4

Description
Frequency of transfer to intensive care unit
Timepoint
Daily for 5-10 days
Method of measurement
Under supervision

Intervention groups

1

Description
Intervention group: Receiving 15 cc daily, three times a day orally of herbal syrups (each 100 ml of syrup prepared from 10 grams of apples, 15 grams of Lonicera, 15 grams of hyssop and 9 grams of yarrow). Patients in this group receive a standard treatment regimen based on the national protocol.
Category
Treatment - Drugs

2

Description
Control group: The group receiving placebo syrup that is given daily in two divided doses. Patients in this group receive a standard treatment regimen based on the national protocol.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Ashayer Hospital
Full name of responsible person
Forouzan Ahmadpour
Street address
Shohadaye Ashayer Hospital, Enghelab Street
City
Khorramabad
Province
Lorestan
Postal code
381351698
Phone
+98 66 3323 6404
Email
shohadahospital@lums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Dr. Ebrahim Fallahi
Street address
Lorestan, Kamalvand, 4 km of Khorramabad road
City
Khorramabad
Province
Lorestan
Postal code
381351698
Phone
+98 66 3312 0239
Email
edu-res@lums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad 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

2

Sponsor

Name of organization / entity
Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences

Full name of responsible person
Forouzan Ahmadpour

Street address
Lorestan, Kamalvand, 4 km of Khorramabad road

City
Khorramabad

Province
Lorestan

Postal code
381351698

Phone
+98 66 3312 0239

Email
edu-res@lums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for Research and Technology of Lorestan 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
Khoram-Abad University of Medical Sciences

Full name of responsible person
Forouzan Ahmadpour

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
Khoram-Abad University of Medical Sciences, km 4 of Khorramabad road

City
Khorramabad

Province
Lorestan

Postal code
381351698

Phone
+98 66 3312 0239

Email
ahmadpourforoz@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Forouzan Ahmadpour

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Khoram-Abad University of Medical Sciences, km 4 of Khorramabad road

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Khorramabad

Province
Lorestan

Postal code
381351698

Phone
+98 66 3312 0239

Email
ahmadpourforoz@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Forouzan Ahmadpour

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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City
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Province
Lorestan

Postal code
381351698

Phone
+98 66 3312 0239

Email
ahmadpourforoz@yahoo.com

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