

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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 Ionicera 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 over 18 years of age with moderate to severe severity of COVID-19 patients admitted to Shohadieh-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 sign 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 Ionicera, 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

ahmadpour.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

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 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

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

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