

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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 sign 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**

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**Province**

Lorestan

**Postal code**

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**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**

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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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### 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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**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