# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 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**
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+98 66 3323 6404
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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
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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**
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

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Lorestan, Kamalvand, 4 km of Khorramabad road

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**Province**
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**Grant name**

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**Is the source of funding the same sponsor organization/entity?**
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**Title of funding source**
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**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

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## Person responsible for scientific inquiries

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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