

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the Effectiveness of Standard Treatment with Standard Treatment plus licorice extract as adjunctive treatment in Improving Respiratory Symptoms and Survival Rate in COVID-19 Patients

#### Protocol summary

##### Study aim

Comparison of the efficacy of standard treatment with standard treatment plus licorice extract as adjunctive treatment on pulmonary symptoms and mortality rate in patients with COVID-19

##### Design

A randomized phase 2 controlled clinical trial on 190 patients with COVID-19

##### Settings and conduct

The study is conducted in four University hospitals in Tehran. The study population is 190 patients with COVID-19. After giving sufficient explanations and obtaining written informed consent from the patient or first-degree relatives (in patients with low consciousness level or dementia), these patients are divided into two groups based on a permuted four-block randomization and a random number table. The first or control group will receive only COVID-19 standard treatment based on the Ministry of Health's recommended protocol. The second group or trial group receive a herbal formulation of licorice in the form of 240 cc syrup at a dose of 10 cc 3 times daily for a maximum of 8 days, in addition to standard treatment.

##### Participants/Inclusion and exclusion criteria

admitted patients with COVID-19 Diagnosis of COVID-19 by lung CT or PCR

##### Intervention groups

Group A are patients receiving standard COVID-19 treatment based on the Ministry of Health's protocol. Group B are patients who receive, in addition to standard treatment, a licorice-based herbal formulation in a 240 cc syrup, at a dose of 10 cc three times daily for a maximum of eight days.

##### Main outcome variables

The duration of hospitalization in survivors.

#### General information

##### Reason for update

We requested to update the trial based on the national scientific committee on Covid-19

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160316027081N1**

Registration date: **2020-03-31, 1399/01/12**

Registration timing: **prospective**

Last update: **2022-03-03, 1400/12/12**

Update count: **2**

##### Registration date

2020-03-31, 1399/01/12

##### Registrant information

##### Name

Saeed Soleiman-Meigooni

##### Name of organization / entity

AJA university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4414 4939

##### Email address

s.s.meigooni@ajaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-23, 1399/01/04

##### Expected recruitment end date

2020-04-20, 1399/02/01

##### Actual recruitment start date

2020-04-01, 1399/01/13

##### Actual recruitment end date

2020-06-01, 1399/03/12

**Trial completion date**

2020-07-01, 1399/04/11

**Scientific title**

Comparison of the Effectiveness of Standard Treatment with Standard Treatment plus licorice extract as adjunctive treatment in Improving Respiratory Symptoms and Survival Rate in COVID-19 Patients

**Public title**

Effect of Licorice in COVID-19

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Admitted patients with COVID-19 in the four hospitals of AJA medical University in Tehran COVID-19 diagnosed by lung CT or naso-pharyngeal PCR

**Exclusion criteria:**

Severe hypersensitivity to the Licorice DKA or NKHC  
Pregnancy Decompensated Cirrhosis Non viral sepsis  
Active GIB Acute trauma or Surgical problem Unstable angina or Acute MI Chronic renal failure with Uremic symptoms

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **190**

Actual sample size reached: **185**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, we use a permuted four-block randomization method. For this purpose six blocks consisting of AABB, ABAB, ABBA, BBAA, BABA, and BAAB are designated and then for each of four patients, one of these blocks will be assigned using the random digit table. In fact, according to the order specified in each block, two patients will receive protocol A (standard treatment of COVID) and two patients will receive protocol B (standard treatment of COVID plus licorice extract).

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of AJA University of Medical Sciences

**Street address**

No 29, 1th Niloufar Ave, Sarv St, East Farsad St, avanmardan Blvd, Shahre Ziba

**City**

Tehran

**Province**

Tehran

**Postal code**

1487784637

**Approval date**

2020-03-18, 1398/12/28

**Ethics committee reference number**

IR.AJAUMS.REC.1398.267

**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**

Admission time

**Timepoint**

Daily

**Method of measurement**

Patients' profile (Yes or no)

**Secondary outcomes**

1

**Description**

C-reactive protein

**Timepoint**

On admission, On discharge

**Method of measurement**

Laboratory test

2

**Description**

differences in lymphocyte count

**Timepoint**

on admission, on discharge

**Method of measurement**  
with the cell counter device

### 3

**Description**  
the death number

**Timepoint**  
at the end of admission

**Method of measurement**  
base on the patient registries

## Intervention groups

### 1

**Description**  
Intervention group: In this group of patients with COVID-19, in addition to standard treatment introduced by the Ministry of Health, the second drug is also prescribed. It is a licorice-based herbal extract that contains licorice, Rheum palmatum, Rosa damascene, Crocus sativus, and Ziziphus jujube. In order to prepare this extract, simple substances of these herbal are first prepared from the pharmaceutical market and after identification in the herbarium of the Faculty of Pharmacy of Tehran University of Medical Sciences, a herbarium code is assigned to each one. Then, a herbal syrup is extracted from these herbs by the maceration method. The syrup is standardized based on glycerol content, the total phenolic, and flavonoids compounds by HPLC method. Microbial controls are performed on the syrup. The syrup is packaged in 240 cc dark pets and given to the patient and at a dose of 10 cc every 8 hours for up to 8 days.

**Category**  
Treatment - Drugs

### 2

**Description**  
Control group: Patients in this group receive only standard treatment provided by the Ministry of Health for COVID-9.

**Category**  
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Be'sat hospital  
**Full name of responsible person**  
Dr.Mohammad Aminianfar  
**Street address**  
Hejrat St, Basij Blvd, Afsarieh  
**City**  
Tehran  
**Province**  
Tehran

**Postal code**  
1781997511  
**Phone**  
+98 21 3995 5555  
**Email**  
maminianfar@yahoo.com

### 2

**Recruitment center**  
**Name of recruitment center**  
Khanevadeh hospital  
**Full name of responsible person**  
Dr.Saeed Soleiman-Meigooni  
**Street address**  
Kaaj St, Shari'ati Blvd  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1613917149  
**Phone**  
+98 21 7760 0500  
**Email**  
dr.saeed.meigooni@gmail.com

### 3

**Recruitment center**  
**Name of recruitment center**  
Imam Reza hospital  
**Full name of responsible person**  
Dr. Ali Asgari  
**Street address**  
E'temad Zadeh Av, Fatemi St  
**City**  
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**Province**  
Tehran  
**Postal code**  
1411718701  
**Phone**  
+98 21 8609 6350  
**Email**  
aliasgari222@gmail.com

### 4

**Recruitment center**  
**Name of recruitment center**  
Golestan hospital  
**Full name of responsible person**  
Dr. Amir Ezzati  
**Street address**  
Sayyad Highway  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1668649551  
**Phone**

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dr\_meigooni@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Ramin Hamidi Farahani

**Street address**

E'temad Zadeh Av, Fatemi St

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**Postal code**

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**Phone**

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**Email**

admin@ajaums.ac.ir

**Web page address**

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Artesh 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**

Artesh University of Medical Sciences

**Full name of responsible person**

Dr. Saeed Soleiman Meigooni

**Position**

Deputy of Research

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

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Javanmardan Bolv, Shahr-e-Ziba

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**Email**

dr.saeed.meigooni@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Dr. Saeed Soleiman-Meigooni

**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

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Dr.saeed.meigooni@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Dr.Saeed Soleiman Meigooni

**Position**

Deputy of Research

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

**Street address**

No 29, 1th Niloufar Alley, Sarv Av, east Farsad St,  
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dr.saeed.meigooni@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Questionnaire

**When the data will become available and for how long**

After one year

**To whom data/document is available**

Deputy of research, Ministry of health

**Under which criteria data/document could be used**

After formal request

**From where data/document is obtainable**

AJA University of medical sciences, deputy of research

**What processes are involved for a request to access data/document**

From: Ministry of Health, Deputy of Research To: AJA University of Medical Sciences

**Comments**

We are not permitted to publish the information of the military patients unprepared.