Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Nov 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)

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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

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Province

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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
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2

Recruitment center
Name of recruitment center
Khanevadeh hospital
Full name of responsible person
Dr.Saeed Soleiman-Meigooni
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3

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
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4

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
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Email

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

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Tehran

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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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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Deputy of Research

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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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.