

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Oct 2026

Comparison of the Effect of Alcoholic Extract of Licorice Root and Placebo Capsule on Alpha Tumor Necrosis Factor (TNF- α) Inflammatory Factor Interleukin-6 (IL-6) and Inflammatory Factor 1-Beta (IL-1 β) in Patients with Covid-19

Protocol summary

Study aim

Determining the effect of licorice root extract on clinical and laboratory symptoms of patients with Covid-19

Design

This study was designed as a double-blind randomized controlled clinical trial (RCT) with placebo.

Settings and conduct

120 samples are selected use blood sampling referred to the affiliated hospitals of Shahid Beheshti University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria :Includes people with laboratory confirmation of Covid virus 19 Age over 15 years
Exclusion criteria Patient request to leave the study for any reason Request the treating physician to exclude the patient from the study for any reason History of drug allergies Patients with hypertension Group of patients with underlying disease

Intervention groups

Alcoholic extract of licorice root will be purchased from Shirin Daroo Company and will be received in sterile packages. Prior to purchase, the manufacturer will receive a Certificate of Sale and Good Manufacturing Practice. The sample will be sent to Zarband Pharmaceutical Company before the final order for glycyrrhizin content analysis and microbial testing, and the result of the analysis will be received. Alcoholic extract of licorice will be obtained from Shirin Daroo company along with COA product analysis sheet. Then a sample of it will be sent to Zardband Pharmaceutical Company for confirmation of the mentioned parameters and final approval according to the standards mentioned in international pharmacopoeias. The microcrystalline cellulose compound under the brand name AVICEL (particle diameter: less than 50 micrometers) will be purchased as a placebo from the pharmaceutical

company (Exir, Iran).

Main outcome variables

Interleukin-six (IL-6), interleukin-one beta (IL-1 β), tumor necrosis factor-alpha (TNF- α), fibrinogen, d-dimer, ferritin, International Normalized Ratio (INR), reaction protein C(CRP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201111049348N1**

Registration date: **2021-01-03, 1399/10/14**

Registration timing: **prospective**

Last update: **2021-01-03, 1399/10/14**

Update count: **0**

Registration date

2021-01-03, 1399/10/14

Registrant information

Name

Shokoofe Noori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2387 2570

Email address

shnoori@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-29, 1399/11/10
Expected recruitment end date
2021-02-18, 1399/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effect of Alcoholic Extract of Licorice Root and Placebo Capsule on Alpha Tumor Necrosis Factor (TNF- α) Inflammatory Factor Interleukin-6 (IL-6) and Inflammatory Factor 1-Beta (IL-1 β) in Patients with Covid-19

Public title
The Effect of Licorice Root Extract on the Treatment of Patients with Covid-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Includes people with laboratory confirmation of Quid 19 virus regardless of clinical signs and close association
Age over 15 years

Exclusion criteria:
Patient request to leave the study for any reason
Request the treating physician to exclude the patient from the study for any reason
History of drug allergies
History of allergies
Patients with immunodeficiency
Patients with hypertension
Group of patients with underlying disease

Age
From 15 years old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: 120
More than 1 sample in each individual
Number of samples in each individual: 2
Blood samples are taken on the first day before the intervention and on the tenth day after the intervention for the main and routine variables of the study.

Randomization (investigator's opinion)
Randomized

Randomization description
In this research, the law of random allocation has been used. Thus, in the above study, with a sample size of 120 people, 60 balls for the intervention group (consumers of capsules containing licorice extract) with the title A and 60 balls for the control group (users of placebo capsules) with the title B were placed in a lottery container. And then randomly for each patient the balls are taken out of

the container without replacement and the sequence created for each patient is recorded.

Blinding (investigator's opinion)

Double blinded

Blinding description

Because the capsule containing licorice extract and the placebo are exactly the same color and size, patients and the research team are unaware of its contents, and only the treating physician knows which patient has taken which capsule.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Velenjak Daneshjo Boulevard Kodakyar Alley

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-10-11, 1399/07/20

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.585

Health conditions studied

1

Description of health condition studied

People with COVID 19 whose disease has been confirmed by Real Time PCR

ICD-10 code

ICD-10 code description

U07.1

Primary outcomes

1

Description

Interleukin 6(IL-6)

Timepoint

Major measurements of variables are performed on the first day before the intervention and on the 10th day after the intervention

Method of measurement

Using the kit

2

Description

Interleukin One Beta(IL-1 β)

Timepoint

Major measurements of variables are performed on the first day before the intervention and on the 10th day after the intervention

Method of measurement

Using the kit

3

Description

Alpha tumor necrosis factor(TNF- α)

Timepoint

Major measurements of variables are performed on the first day before the intervention and on the 10th day after the intervention

Method of measurement

Using the kit

Secondary outcomes

1

Description

The international normalized ratio (INR)

Timepoint

Sampling is done on the first day before the intervention and on the 10th day after the intervention for the main and routine variables of the study.

Method of measurement

Through a clinical laboratory

2

Description

D -Dimmer

Timepoint

Sampling is done on the first day before the intervention and on the 10th day after the intervention for the main and routine variables of the study.

Method of measurement

Through a clinical laboratory

3

Description

Fibrinogen

Timepoint

Sampling is done on the first day before the intervention and on the 10th day after the intervention for the main and routine variables of the study.

Method of measurement

Through a clinical laboratory

4

Description

Ferritin

Timepoint

Sampling is done on the first day before the intervention and on the 10th day after the intervention for the main and routine variables of the study.

Method of measurement

Through a clinical laboratory

5

Description

C Reactive Protein (CRP)

Timepoint

Sampling is done on the first day before the intervention and on the 10th day after the intervention for the main and routine variables of the study.

Method of measurement

Through a clinical laboratory

Intervention groups

1

Description

Consumption of capsules containing licorice extract in the intervention group. Alcoholic extract of licorice root will be purchased from Shirin Daroo Company and will be received in sterile packages. Prior to purchase, the manufacturer will receive a Certificate of Sale and Good Manufacturing Practice. The received sample will be sent to Zarband Pharmaceutical Company before the final order for glycyrrhizin content analysis and microbial test and the result of the analysis will be received. Alcoholic extract of licorice will be obtained from Shirin Daroo company along with COA product analysis sheet. Then, the sample will be sent to Zardband Pharmaceutical Company for confirmation of the mentioned parameters and final approval according to the standards mentioned in international pharmacopoeias. The extract will be added and mixed thoroughly. The powder obtained in the pharmaceutical factory (Osweh, Iran) will be packaged in an orange gelatin capsule (400 mg) and in a brown opaque can. Capsules containing licorice extract will be taken for one month in the amount of one capsule the day after lunch with a glass of water.

Category

Placebo

2

Description

Control group: Placebo in capsules with the same color and size as the drug in cans similar to capsules containing licorice. Microcrystalline cellulose composition under the brand name AVICEL (particle diameter: less than 50 micrometers) as a placebo from the pharmaceutical company (Elixir, Iran) will be purchased. Placebo capsules will be taken for one month in the amount of one capsule per day after lunch with a glass of water.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Subsidiary hospitals of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mrs Shokofe Noori

Street address

Student Boulevard, Arabi Alley

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Tehran

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1985711151

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Email

taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research, Dr.Afshin Zarghi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mrs Shokofe Noori

Position

Associate Professor Shahid Beheshti University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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shnoori85@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mrs Shokofe Noori

Position

Associate Professor Shahid Beheshti University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mrs Shokofe Noori

Position

Associate Professor Shahid Beheshti University of
Medical Sciences

Latest degree

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because patient information is private and not available
to the public

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

Patients' personal data is private and not available to the
public, but the data and results of their analysis will be
made available to the public.

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

Unlimited

To whom data/document is available

public

Under which criteria data/document could be used

To improve people's knowledge about whether licorice
consumption modulates the clinical symptoms of COVID
19 patients.

From where data/document is obtainable

Databases

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

Refer to the database and access to information

Comments