Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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-1β) 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-1β), 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-1β) 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-1β)
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

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Student Boulevard, Arabi Alley

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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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Koodkiar Street, Student Boulevard, Velenjak

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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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Position
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Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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Other areas of specialty/work
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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