

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Sep 2021

Evaluation the effect of aqueous extract of licorice on coronavirus outpatients: A randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim

Effect of aqueous extract of licorice in coronavirus outpatients

Design

Randomized, blinded, placebo controlled clinical trial. Effect of licorice capsules in 20 patients which have inclusion criteria will be evaluated. Simultaneously, 20 patients will take placebo. Medicine and placebo in the same form and package with the alphabets A and B will be delivered to physicians and patients. Patients must take the capsules three times a day for 14 days

Settings and conduct

Randomized, blinded, placebo controlled clinical trial will be in Mashhad. Effect of licorice capsules in 20 patients with coronavirus disease which have inclusion criteria will be evaluated. Simultaneously 20 patients will take placebo. Medicine and placebo in the same form and package with the alphabets A and B will be delivered to physician and patients. The patients must take the capsules three times a day for 14 days

Participants/Inclusion and exclusion criteria

Inclusion criteria: The outpatients in quarantine, take medicine, diagnosed for coronavirus disease according to clinic (fever, cough, myalgia) and paraclinical parameters (lymphopenia, increase CRP). Exclusion criteria: Sensitivity to licorice and its derivatives; below 18 and above 65 years old; hepato, renal or respiratory disorders; take cytotoxic, corticosteroid drugs; nursing or pregnant women

Intervention groups

Effect of licorice capsules in 20 patients which have inclusion criteria will be evaluated. Simultaneously 20 patients which have inclusion criteria will take placebo.

Main outcome variables

Time interval until lymphopenia improves Time interval until CRP normalizes Time interval until clinical symptoms improve (fever, cough and myalgia)

General information

Reason for update

Acronym

LCS

IRCT registration information

IRCT registration number: **IRCT20200404046933N1**

Registration date: **2020-04-12, 1399/01/24**

Registration timing: **prospective**

Last update: **2020-04-12, 1399/01/24**

Update count: **0**

Registration date

2020-04-12, 1399/01/24

Registrant information

Name

Gholamreza Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 1191

Email address

karimig@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of aqueous extract of licorice on coronavirus outpatients: A randomized, double-blind, placebo-controlled clinical trial

Public title

Evaluation the effect of licorice for treatment of coronavirus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed for coronavirus according to clinic such as fever, cough and myalgia Patients diagnosed for coronavirus according to paraclinic such as lymphopenia and increase of CRP Patients in the range of 18-65 years old

Exclusion criteria:

Sensitivity to licorice and it derivatives Patients with hepato, renal or respiratory disorders Patients who take cytotoxic or corticosteroid drugs Nursing or pregnant women

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in three stages: 1- Generation simple or limited randomization will be done based on a table of random numbers 2- Allocation concealment: which is done in the form of coded boxes (numbered drug containers) with a random sequence. In this method, a number of boxes with the same shape and size are numbered based on random sequences and contain drugs or placebo that have a completely similar appearance. 3- Execution of random allocation process: A: Identify the person who creates the random sequence B: A person who evaluates and registers researchers in terms of inclusion and exclusion criteria C: The person who assigned the participants to the groups: infectious diseases specialist The main researcher of the project, who creates a random sequence, does not interfere in other stages of randomization, including registration and allocation of participants, and the person involved in creating a random program is separate from other researchers.

Blinding (investigator's opinion)

Double blinded

Blinding description

the medicine in the form of similar capsule but with the alphabetic A or B will be delivered to physician and patients

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee of Mashhad University of Medical Sciences

Street address

Blv.Vakilabad 2- School of Pharmacy-1365-91775

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Approval date

2020-04-05, 1399/01/17

Ethics committee reference number

IR.MUMS.REC.1399.047

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.1

ICD-10 code description

Covid-19 disease

Primary outcomes

1

Description

Time interval until clinical symptoms improve

Timepoint

3 days, 1 week and 2 weeks after treatment

Method of measurement

Time of recovery

2

Description

Lymphopenia

Timepoint

3 days, 1 week and 2 weeks after treatment

Method of measurement

Cell counter device

3

Description

CRP level

Timepoint

3 days, 1 week and 2 weeks after treatment

Method of measurement

CRP kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to the standard treatment regimen for covid-19, capsules which have aqueous licorice extract containing 80 mg of the active ingredient glycyrrhizin will be given three times a day for 2 weeks. Licorice capsules are formulated at the Mashhad School of Pharmacy with the ineffective ingredients of Ovisil and Arozil

Category

Treatment - Drugs

2

Description

Control group: In addition to general drugs for treatment of corona, the patients take placebo capsule 3 times a day for 14 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam reza hospital

Full name of responsible person

Dr. Dehghan Nayeri

Street address

Imam reza square

City

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Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

DehghanMJ@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Daneshgah avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3854 1538

Email

tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Gholamreza Karimi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Gholamreza Karimi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Professor

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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

Not applicable