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 extarct 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. Simultanously, 20 patients will take placebo. Medicine and placebo in the same form and package with the alphabetics A and B will be deliverd to physiciana 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. Simultanously 20 patients will take placebo. Medicine and placebo in the same form and package with the alphabetics A and B will be deliverd 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 paraclinic parameters (lymphopenia, increase CRP). Exclusion criteria: Sensitivity to licorice and it 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. Simultanously 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 mylagia 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 alphabetics 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:]n 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
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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
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9138813944
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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

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Mashhad University of Medical Sciences

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Position
Professor

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Medical Pharmacy

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Person responsible for updating data

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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