

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2020

Evaluation of the effects of Licorice on clinical symptoms and laboratory signs in patients with COVID-19: An open-label randomized clinical trial

Protocol summary

Study aim

Evaluation of the effects of Licorice on clinical symptoms and laboratory signs in patients with COVID-19

Design

Controlled clinical trial with parallel group, open-label, phase 3, 60 patients, simple randomized method

Settings and conduct

This study will be conducted at the Shahid Mohammadi Hospital, Hormozgan University of Medical Sciences, Bandar Abbas. The study population is 60 patients with COVID-19 (30 patients in control group and 30 in study group).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with positive polymerase chain reaction (PCR) test for COVID-19 or/and lung involvement in imaging, age ≥ 18 years, primary clinical symptoms, hospitalization, and signing informed consent. Exclusion Criteria: Patients with underlying diseases, including heart disease, chronic hypertension, severe renal and liver failure, and thyroid disorders, Use of warfarin, SSRIs, MAOIs, diuretics, corticosteroids, and antiarrhythmic drugs, history of drug allergy, and pregnancy and breastfeeding

Intervention groups

Group A will be patients receiving standard treatment of COVID-19 according to the Ministry of Health's protocol. Group B will be patients receiving, in addition to the standard treatment, a licorice-based herbal tablet, at a dose of 760 mg three times a day for a period of 14 days.

Main outcome variables

Checking the fever, respiratory rate, O₂ saturation
Evaluation of white blood cell count, C-reactive protein
Occurrence of adverse drug reactions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200506047323N2**

Registration date: **2020-05-31, 1399/03/11**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-31, 1399/03/11**

Update count: **0**

Registration date

2020-05-31, 1399/03/11

Registrant information

Name

Mohammad Fathalipour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of Licorice on clinical symptoms and laboratory signs in patients with COVID-19: An open-label randomized clinical trial

Public title

Effects of Licorice in treatment of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age \geq 18 years Positive polymerase chain reaction (PCR) test for COVID-19 or/and lung involvement in imaging Primary clinical symptoms Hospitalized Signing informed consent and willingness of study participant to accept randomization to any assigned treatment arm

Exclusion criteria:

Underlying diseases (heart disease, chronic hypertension, severe renal failure, severe liver failure, and thyroid disorders) Use of warfarin, SSRIs, MAOIs, diuretics, corticosteroids, and antiarrhythmic drugs History of drug allergy Pregnancy and breastfeeding

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method and table of random numbers will be used. If selected number is even, the patient is allocated to treatment group, and if it is odd, the patient is allocated to control group.

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 Hormozgan University of Medical Sciences

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Jomhuri Eslami Blvd

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Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Approval date

2017-05-06, 1396/02/16

Ethics committee reference number

IR.HUMS.REC.1399.066

Health conditions studied**1****Description of health condition studied**

COVID-19 disease

ICD-10 code

U07.2

ICD-10 code description

COVID-19, virus not identified

Primary outcomes**1****Description**

Body temperature

Timepoint

Before intervention and daily during the study

Method of measurement

Thermometer

2**Description**

Respiratory rate

Timepoint

Before intervention and daily during the study

Method of measurement

Respiratory Count

3**Description**

Oxygen saturation

Timepoint

Before intervention and daily during the study

Method of measurement

Pulse oximeter

Secondary outcomes**1****Description**

Lymphocytopenia

Timepoint

Before intervention and days 7 and 14 after the intervention

Method of measurement

Cell count

2**Description**

C-reactive protein

Timepoint

Before intervention and days 7 and 14 after the intervention

Method of measurement

C-RP kit

3**Description**

Incidence of serious adverse events

Timepoint

Before intervention and daily during the study

Method of measurement

Questionnaire

Intervention groups**1****Description**

Intervention group: The standard treatment regimen for COVID-19 based on the Ministry of Health's protocol, including hydroxychloroquine sulfate (Amin Pharmaceutical company, Isfahan) at a dose of 200 mg twice a day, along with a licorice-based herbal medicine (D-REGLIS 380 mg tablets, registration number: 4750956176234914, Irandarouk Pharmaceutical Company) at a dose of 760 mg three times a day for a period of 14 days

Category

Treatment - Drugs

2**Description**

Control group: Standard treatment for COVID-19 based on the Ministry of Health's protocol, including hydroxychloroquine sulfate (Amin Pharmaceutical company, Isfahan) at a dose of 200 mg twice a day for a period of 14 days.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Mohammadi Hospital

Full name of responsible person

Parivash Davoodian

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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

No

Title of funding source

Hormozgan 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**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Mohammad Fathalipour

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Parivash Davoodian

Position

Associate professor

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Mohammad Fathalipour

Position

Consultant

Latest degree

Ph.D.

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

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

No - There is not a plan to make this available

Title and more details about the data/document

Information regarding the study outcomes will be shared.

When the data will become available and for how long

Data will become available after publication of obtained results

To whom data/document is available

Only academic institutions

Under which criteria data/document could be used

The study protocol or proposal should be approved by Ethics committee of institutions. The rights of authors and sponsors should be respected.

From where data/document is obtainable

M.fathalipour@yahoo.com M.fathalipour@hums.ac.ir

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

این درخواست باید خطاب به معاونت تحقیقات و فناوری دانشگاه علوم پزشکی هرمزگان باشد و با اطلاع مجری طرح انجام می شود.

Comments