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)

Phone
+98 76 3371 0406

Email address
m.fathalipour@hums.ac.ir

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 ≥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
Street address
Jomhuri Eslami Blvd
City
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
Street address
Jomhuri Eslami Blvd
City
Bandar Abbas
Province
Hormozgan
Postal code
7919915519
Phone
+98 76 3334 7000
Fax
+98 76 3334 5003
Email
shmh@hums.ac.ir
Web page address
http://shmh.hums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Teamur Aghamolaei
Street address
Jomhuri Eslami Blvd
City
Bandar Abbas
Province
Hormozgan
Postal code
7919915519
Phone
+98 76 3333 3280
Fax
+98 76 3334 6994
Email
mail@hums.ac.ir
Web page address
http://hums.ac.ir/
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
Street address
Emam Hossein Blvd
City
Bandar Abbas
Province
Hormozgan
Postal code
7919691982
Phone
+98 76 3371 0406
Fax
+98 76 3371 0389
Email
m.fathalipour@hums.ac.ir

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
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
Street address
Jomhuri Eslami Blvd
City
Bandar Abbas
Province
Hormozgan
Postal code
7919915519
Phone
+98 76 3333 3280
Email
parivash.davoodian@hums.ac.ir

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.
Other areas of specialty/work
Medical Pharmacy
Street address
Emam Hossein Blvd
City
Bandar Abbas
Province
Hormozgan
Postal code
7919691982
Phone
+98 76 3371 0406
Fax
+98 76 3371 0389
Email
m.fathalipour@hums.ac.ir

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