Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation of the effects of the aqueous extract of Alhagi papilionaceae or petals Saffron petal and mountain tea herbs on the clinical and paraclinical symptoms of COVID-19 patients

Protocol summary

Study aim

Evaluation of the effects of the aqueous extract of Alhagi papilionaceae or petals Saffron petal and mountain tea herbs on the clinical and paraclinical symptoms of COVID-19 patients

Design

Clinical trial with control group, double blind, randomized, phase 2on 40 patients. With the help of a statistician as well as the use of appropriate software (probably SAS Version 9.2 (SAS institute Inc., Cary, NC))

Settings and conduct

Blood samples will be collected from patients. Liver and kidney function are assessed in patients. Includes assessment of length of hospital stay, mortality rate, and pulmonary infiltration rate based on X-ray or CT scan of the lungs. It will be prescribed to patients by a doctor and will be performed in Ali Ibn Abitaleb Hospital in Rafsanjan

Participants/Inclusion and exclusion criteria

Inclusion criteria in this study included all patients in whom Covid 19 infection was confirmed. Exclusion criteria included patients with other infections or diseases such as influenza, pulmonary insufficiency, ARDS pneumonia and other cold symptoms.

Intervention groups

The intervention group includes patients with COVID-19 who receive herbal compounds (including aqueous extract of Ador-Cancer, saffron petals and mountain tea). The control group includes patients with COVID-19 who receive placebo

Main outcome variables

Duration of hospitalization of patients with Covid-19 Mortality rate of patients with Covid-19 Pulmonary infiltration rate in patients with Covid-19

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211108053002N1**
Registration date: **2021-11-21, 1400/08/30**
Registration timing: **prospective**

Last update: **2021-11-21, 1400/08/30**
Update count: **0**

Registration date

2021-11-21, 1400/08/30

Registrant information

Name

ALI darehkordi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3131 5000

Email address

adarehkordi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effects of the aqueous extract of Alhagi papilionaceae or petals Saffron petal and mountain tea herbs on the clinical and paraclinical symptoms of COVID-19 patients

Public title
Evaluation of the effect of plant compounds extract (including aqueous extract of Ador-Cancer, saffron petals and mountain tea) in patients with coronary disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Inclusion criteria in this study include all patients who have been diagnosed with Covid 19 infection and do not have other infections or diseases such as influenza, pulmonary insufficiency, ARDS pneumonia and other cold symptoms, as well as files with complete data. Consciously taken from patients.

Exclusion criteria:
Exclusion criteria included patients who had other infections or diseases such as influenza, pulmonary insufficiency, ARDS pneumonia and other cold symptoms and the result of Qovid 19 infection is negative. Also, files with incomplete data will be removed from this study. Obviously, conscious dissatisfaction also leads to exclusion from the study. Patients who were hospitalized and their clinical condition was deteriorating were excluded from the study and lung CT scans were obtained from patients. Patients with oxygen levels less than 93 mm Hg were excluded from the study

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method and description: Simple randomization Randomization unit: individual Randomization tool: Excel software How to build a random sequence: Using the Excel Rand function Hide: In order to hide random allocation, the method of SNOSE will be used.

Blinding (investigator's opinion)
Double blinded

Blinding description
Thus, drug and placebo syrups will be prepared in one form and one form and will be prescribed to patients by the doctor. Syrups have codes that neither the doctor nor the researcher knows about. Also, data collection is done by a researcher who does not know the divided group. In addition, the people who will analyze the data will be unaware of the content of the groups. Thus, neither the patient, nor the researcher, nor the physician, nor the data analyst will know the content of the groups. Patients are also asked not to talk about their treatment with other patients. The patient code will be opened only in emergency situations and when the possible side effects of taking the drug make it necessary to change the treatment protocol. Data entry software will be locked so data access or change will not be possible. Monitoring and control An independent supervisor will be asked to check all questionnaires and make sure the consent forms are signed. Also, a number of patients will be randomly selected and asked about the treatment protocol.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of University of Medical Sciences

Street address
Persian Gulf Boulevard - Pistachio Boulevard - Campus of Molecular Medical Research Center

City
rafsanjan

Province
Kerman

Postal code
7718175911

Approval date
2021-06-19, 1400/03/29

Ethics committee reference number
IR.RUMS.REC.1400.097

Health conditions studied

1

Description of health condition studied
symptoms of COVID-19 patients

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
The length of hospitalization of patients with Covid-19
Timepoint
21 days after starting of intervention
Method of measurement
By referring to the patient's medical record

2

Description
The mortality in patients with Covid-19
Timepoint
21 days after starting of intervention
Method of measurement
By referring to the patient's medical record

3

Description
The pulmonary infiltration in patients with Covid-19
Timepoint
7, 14 and 21 days after starting of intervention
Method of measurement
With CT scan

Secondary outcomes

1

Description
Side effects from the use of herbal compounds (COVID-herbs)
Timepoint
7, 14 and 21 days after starting of intervention
Method of measurement
Refer to the medical file and complete a special questionnaire for complications

2

Description
The liver function in patients with Covid-19
Timepoint
7, 14 and 21 days after starting of intervention
Method of measurement
Evaluation of SGOT and SGPT enzymes using ELISA kit

3

Description
The kidney function in patients with Covid-19
Timepoint
7, 14 and 21 days after starting of intervention
Method of measurement
Evaluation of chemical parameters such as BUN and Creatinine by colorimetric method with autoanalyzer

Intervention groups

1

Description
Intervention group: Patients with Covid-19 will consume 10 ml of syrup containing aqueous extracts of Ador-Cancer, saffron petals and mountain tea 3 times a day. In this study, no special equipment is used and the explanations of this trial are given in printed form to the volunteers. Entry to this study does not require special training. Herbal extract syrup is prepared and approved in Rafsanjan University of Medical Sciences.
Category
Treatment - Drugs

2

Description
Control group: Control group: Yamaran with Covid-19 will take 10 ml of placebo 3 times a day. In this study, no special equipment is used and the explanations of this trial are given in printed form to the volunteers. Entry to this study does not require special training. The placebo is prepared and approved at Rafsanjan University of Medical Sciences.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Patients who have been hospitalized
Full name of responsible person
Ziba Shabani
Street address
Persian Gulf Boulevard
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+98 34 3131 5000
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Email
adarehkordi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
ali darekordi
Street address
Persian Gulf Boulevard

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Email
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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
Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Ali Drehkordi
Position
Faculty
Latest degree
Ph.D.
Other areas of specialty/work
chemistry
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Pistachio Boulevard
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mojgan.noroozi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
ali darekordi
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
ali darekordi
Position
حقخبثسسخق
Latest degree
Ph.D.
Other areas of specialty/work
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mojgan.noroozi@yahoo.com

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

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

Part of the data, such as information about the main outcome, can be shared.

When the data will become available and for how long

After the publication of the article, all data will be available to all researchers indefinitely

To whom data/document is available

Everyone

Under which criteria data/document could be used

For research work

From where data/document is obtainable

Refer to the project manager and send an email Dr. Ali Darreh Kurdi adarehkordi@yahoo.com

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

Formal request to the university and then refer to the project manager

Comments