Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the effect of CRSM-X7 herbal therapeutic supplement in the improving of symptoms of patients with COVID-19 hospitalized in the medical centers.

Protocol summary

Study aim
Determining the effect of CRSM-X7 as a herbal therapeutic supplement on the improvement of COVID-19 disease symptoms

Design
Clinical trial with parallel control group, non-blinded, randomized, phase 3-2 on 200 patients. For randomization Block method was used.

Settings and conduct
Using the formula for calculating the sample size, 200 patients referring to the medical centers of Baqiyatallah University of Medical Sciences will enter the study. 100 people in the intervention group receive a standard treatment regimen + herbal supplement, and 100 people in the comparison group receive only the same standard treatment regimen as the intervention group. There is no blinding in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of COVID-19 Age 18-65 Having informed and written consent to participate in the study Exclusion criteria: Disagreement of the physician directly responsible for the patient Pregnancy and breastfeeding Allergies to the drug elements Symptoms of gastrointestinal, liver or kidney disease Incidence of drug interactions Hypertension Having heart failure Do not take anticoagulants

Intervention groups
The intervention group includes patients with COVID-19 disease who receive the standard treatment regimen intervention + herbal therapeutic supplement of CRSM-X7. The comparison group includes patients with COVID-19 disease receiving standard dietary intervention.

Main outcome variables
Duration of hospitalization Fever The need for ICU admission Incidence of ARDS Intubation requirements Patient expire rate O2 saturation Body pain Cough Olfactory Sense of taste computed tomography scan

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210325050769N1**
Registration date: **2021-04-12, 1400/01/23**
Registration timing: **prospective**

Last update: **2021-04-12, 1400/01/23**
Update count: **0**

Registration date
2021-04-12, 1400/01/23

Registrant information
Name
Mohammad Heiat
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-19, 1400/01/30
Expected recruitment end date
2021-07-22, 1400/04/31
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of CRSM-X7 herbal therapeutic supplement in the improving of symptoms of patients with COVID-19 hospitalized in the medical centers.

Public title
Evaluation of the effect of herbal therapeutic supplements (Marsh - Mallow, Sweet violet, Malva sylvestris, Damask rose, Liquorice root) against corona disease

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of COVID-19 Age 18-65 Having informed and written consent to participate in the study

Exclusion criteria:
Disagreement of the physician directly responsible for the patient Pregnancy and breastfeeding Allergies to the drug elements Symptoms of gastrointestinal, liver or kidney disease Incidence of drug interactions Patient dissatisfaction to continue the project for any reason Inability of the patient to receive oral medication Hypertension Having heart failure Do not take anticoagulants (aspirin, Plavix, warfarin)

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

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: block, Randomization unit: individual Randomization layers: age, sex, disease severity Randomization tool: A sealed envelope containing the number of blocks How to build a sequential image: based on blocks with size of 4 and 6 .

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
Research Ethics Committee of Baqiyatallah University of Medical Sciences

Street address
Mollasadra-south Shikh bahaei

City
Tehran

Province
Tehran

Postal code
1939-55487

Approval date
2020-10-12, 1399/07/21

Ethics committee reference number
IR.BMSU.REC.1399.400

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
hospitalization time

Timepoint
Before starting the study and after 5 days of using herbal supplements

Method of measurement
A researcher-made questionnaire whose validity and reliability have been assessed

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The drug (including tea, honey and royal jelly for 5 days) is delivered to the hospital along with the list of codes of patients in the intervention group (to be presented to patients in the intervention group).The composition inside each CRSM-X7 tea bag includes 10 grams of marshmallow, 5 grams of Sweet violet, 5 grams of Wild mallow, 5 grams of Damask rose, 10 grams of Liquorice root. After identification and registration, they will be placed in special bags for use. Each bag of CRSM-X7 herbal tea is infused in a volume of

300 ml of boiling water for one day use. After the temperature of the drink is reduced (it reached the temperature of 40 ° C), 5 cc of lavender honey is added, dissolved in it and drunk. So that, three glasses (each glass is equivalent to 100 ml) will be drunk per day (half an hour before breakfast, one hour before lunch, one hour before bedtime) up to five days by the intervention group. The seventh element of this supplement is Royal Jelly, which is prepared in the proportion of 50 grams of Royal Jelly in one kilo gram of lavender honey and should be used by the people under study 4 meals a day, ie morning, noon, evening, night for 5 days (each Promise of 2.5 cc).

Category

Treatment - Other

2

Description

Control group: Control group: 92 people are in the control group, which includes other patients and hospitalized in the same treatment center who receive a standard treatment regimen similar to the intervention group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Baqiyatallah Hospital

Full name of responsible person
Mohammad Ali Abyazi Haris

Street address
Mollasadra-South Sheikh bahaei

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Ahmad-Reza Sharifi Alvan Abadi

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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
Iranian Matin Gene Co.

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Ahmad-Reza Sharifi Alvan Abadi

Position
Faculty Member

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Person responsible for scientific inquiries

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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
Not applicable

Title and more details about the data/document
All study documents which includes the variables studied in the studywill be shared and made available after the publication of the article, without any conditions.

When the data will become available and for how long
The access period will start after the article is published in a scientific journal

To whom data/document is available
All people, including researchers working in academic and scientific institutions, or people working in industry, will be able to access the data.

Under which criteria data/document could be used
Once the article has been published in an international journal, there are no preconditions for accessing the data to perform any type of analysis on the delivered data.

From where data/document is obtainable
Baqiyatallah University of Medical Sciences, Traditional Medicine Research Center / Gastroenterology and Liver Research Center

What processes are involved for a request to access data/document
After the data is published in an international journal, information will be provided with a simple, basic written request without any formalities.
Mohamad.heiat@gmail.com

Comments