

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 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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+98 21 8126 2072

Email address

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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

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Mollasadra-South Sheikh bahaei

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yashar862@gmail.com

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

Street address

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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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Full name of responsible person

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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 study will 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

Person responsible for updating data

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mohammad Heiat

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Internal Medicine

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