Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of barely-based traditional remedy on controlling of clinical symptoms and paraclinical results in hospitalized patients with COVID-19

Protocol summary

Study aim
Evaluating the effect of barley-based product on controlling the symptoms of hospitalized patients with COVID-19 and the recovery process

Design
Randomized parallel clinical trial with control group, phase 3, design of 60 patients, random allocation software was used for randomization.

Settings and conduct
Sixty hospitalized patients with a positive nasopharyngeal PCR test or a suspected chest CT scan are randomly assigned to one of the two groups of barley-based remedy or control. Patients in the intervention group, in addition to the usual treatments, receive a glass of barley-based remedy twice a day for 5 days. The consequences of the study, including laboratory results, clinical signs, and chest x-rays, are measured daily for 5 days

Participants/Inclusion and exclusion criteria
Inclusion criteria: Confirming informed consent and Positive Nasopharyngeal RT-PCR Test or CT Chest
Exclusion criteria: Intubated or hospitalized patient in ICU, pregnant and lactating women, diabetic patients, patients treated with corticosteroids or immunosuppressive drugs, patients undergoing dialysis, use of herbal medicines or other traditional and complementary medicine methods

Intervention groups
Intervention group: Receiving conventional medicine and receiving barley-based remedy for 5 days twice a day and one glass each time Control group: Receiving common medicine drugs

Main outcome variables
Laboratory results (number of lymphocytes, CRP), clinical symptoms (fever, cough, myalgia, shortness of breath, chills) Chest x-ray

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180923041093N6**
Registration date: **2020-06-11, 1399/03/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-11, 1399/03/22**
Update count: **0**

Registration date
2020-06-11, 1399/03/22

Registrant information
Name
Fatemeh sadat Hasheminasab
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 5333 8547
Email address
hashemifa67@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-05-13, 1399/02/24
Expected recruitment end date
2020-06-18, 1399/03/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of barely-based traditional remedy on controlling of clinical symptoms and paraclinical results in hospitalized patients with COVID-19

Public title
The efficacy of barely-based traditional remedy on COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Suffering from COVID-19 based on Positive nasopharyngeal RT-PCR test or CT of the chest 18 years old or more Informed consent

Exclusion criteria:
Intubated patient or hospitalized in the ICU Pregnant and lactating women Diabetes Patients treated with corticosteroids or immunosuppressive drugs Use of herbal medicines or other traditional and complementary medicine methods Dialysis

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
Patients will be selected according to the inclusion criteria and then randomly assigned to the experimental and control groups according to the random sequence obtained through random allocation software (random blocking method with 4 blocks).

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 Shahid Beheshti University of Medical Sciences

Street address
Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
19839-63113

Approval date
2020-05-02, 1399/02/13

Ethics committee reference number
IR.SBMU.RETECH.REC.1399.074

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19

Primary outcomes

1

Description
Tempreture

Timepoint
Daily

Method of measurement
Thermometer

2

Description
Cough

Timepoint
Daily

Method of measurement
Fisman scale

3

Description
Respiratory rate

Timepoint
Daily

Method of measurement
Counting the number of breaths per minute

4

Description
Weakness

Timepoint
Daily

Method of measurement
Visual analog scale

5

Description
Muscular pain
Timepoint
Daily
Method of measurement
Visual analog scale

6

Description
C Reactive Protein (CRP)
Timepoint
Daily
Method of measurement
Blood test

7

Description
Lymphocyte count
Timepoint
Daily
Method of measurement
Blood test

8

Description
O2 Saturation percentage (SpO2)
Timepoint
Daily
Method of measurement
Pulse oximetery

9

Description
Chest X ray
Timepoint
Daily
Method of measurement
Analysis of radiography

Secondary outcomes

1

Description
Number of admission days
Timepoint
Daily
Method of measurement
Counting admission days

2

Description
Mortality
Timepoint
Daily
Method of measurement
The ratio of death to total patients in each group

3

Description
Adverse effect
Timepoint
Daily
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: They receive both usual treatments (Fifth Edition of the Novel Corona Virus Guidelines: hydroxychloroquine/chloroquine phosphate with or without lopinavir/ritonavir or atazanavir/ritonavir) and barley-based remedy (water extract of barely, jujube and lasura) 200 cc, two times a day for 5 days.
Category
Treatment - Drugs

2

Description
Control group: They receive only usual treatments based on classical medicine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospital Mofateh
Full name of responsible person
Roshanak Mokaberinejad
Street address
Faculty of Traditional Medicine, Shams Alley, opposite Tavanir St, above Saei Park, Valiasr Ave.
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8877 3521
Email
mokaberi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

Street address
Next to Ayatollah Taleghani Hospital، Shahid Arabi street, Velenjak, Shahid Chamran highway

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2243 9781

Email
Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Roshanak Mokaberinejad

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
Faculty of Traditional Medicine, Shams Alley, opposite Tavanir St, above Saei Park, Valiasr Ave.

City
Tehran

Province
Tehran

Postal code
1991953381

Phone
+98 21 8877 3521

Email
mokaberi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mahmood Khodadoost

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
No 8, Shams Alley, Opposite Tavanir, Valiasr Ave.

City
Tehran

Province
Tehran

Postal code
1516745811

Phone
+98 21 8877 3521

Email
mkhodadoost@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Roshanak Mokaberinejad

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Faculty of Traditional Medicine, Shams Alley, opposite Tavanir St, above Saei Park, Valiasr Ave.

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Postal code
1991953381

Phone
+98 21 8877 3521

Email
mokaberi@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

After completion of the study, information on the main outcome will be shared

When the data will become available and for how long

6 months after the publication of the article

To whom data/document is available

Researchers

Under which criteria data/document could be used

Data and results will be available to all researchers for corona research.

From where data/document is obtainable

Email to mokaberi@sbmu.ac.ir

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

The data will be provided to the applicant within one month after reviewing and confirming the request.

Comments