

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Oct 2020

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

Temperature

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 oximetry

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

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

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