

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 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.

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## 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

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

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## 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.

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Traditional Medicine

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**Email**

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## 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](mailto: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**