

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Investigating the effect of hot foot-bath on controlling the symptoms of hospitalized patients with COVID-19 and accelerating the recovery process

#### Protocol summary

##### Study aim

Assessing the effect of hot foot bath on controlling the symptoms of hospitalized patients with COVID-19 and accelerating the healing process

##### Design

Randomized controlled clinical trial

##### Settings and conduct

Sixty hospitalized patients with a positive nasopharyngeal PCR test or suspected chest CT or chest X ray are randomly located in one of two groups of warm-water foot bath or control groups. Patients in the intervention group, in addition to the usual treatments, receive foot bath (warm water at 42 C for 20 minutes and then kept warm for 5 minutes) once a day for 7 days. The consequences of the study, including laboratory results, clinical signs, and chest CT scans, are measured at the time of admission and during the study until the end of day 7.

##### Participants/Inclusion and exclusion criteria

Patients enter the study with a positive nasopharyngeal RT-PCR test or positive chest CT scan or chest X ray. Patients cannot enter the study if they are intubated or hospitalized in the ICU, pregnancy and lactation, treatment with corticosteroids or immunosuppressive drugs, or the use of herbal medicines or other traditional and complementary medicine methods.

##### Intervention groups

Intervention group: They receive both usual treatments and foot bath (warm water at 42 C for 20 minutes and then kept warm for 5 minutes once a day for 7 days).  
Control group: They receive only They receive based on classical medicine.

##### Main outcome variables

Laboratory results (number of lymphocytes, CRP), clinical symptoms (fever, cough, myalgia, shortness of breath, chills), chest CT scan and anxiety

#### General information

##### Reason for update

adding (hot foot bath) to Persian title

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180923041093N5**

Registration date: **2020-04-10, 1399/01/22**

Registration timing: **prospective**

Last update: **2020-04-21, 1399/02/02**

Update count: **1**

##### Registration date

2020-04-10, 1399/01/22

##### 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

2020-04-15, 1399/01/27

##### Expected recruitment end date

2020-05-16, 1399/02/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Investigating the effect of hot foot-bath on controlling the symptoms of hospitalized patients with COVID-19 and accelerating the recovery process

### Public title

Evaluation the efficacy of hot foot-bath on COVID-19

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Conscious satisfaction Positive naso-pharyngeal RT-PCR test or chest CT scan or chest X ray

#### Exclusion criteria:

Intubated patients or those admitted in ICU Pregnancy or lactation Patients treated with corticosteroids or immunosuppressive drugs Use herbal medicines or other traditional and complementary medicine methods

### Age

No age limit

### Gender

Both

### Phase

3

### Groups that have been masked

No information

### Sample size

Target sample size: 60

### Randomization (investigator's opinion)

Randomized

### Randomization description

By random blocking method with 4 blocks and using Random Allocation Software

### 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

2020-04-05, 1399/01/17

##### Ethics committee reference number

IR.SBMU.RETECH.REC.1399.029

## 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**  
Anxiety  
**Timepoint**  
Daily  
**Method of measurement**  
Beck questionnaire

## 10

**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

## Intervention groups

### 1

**Description**  
Intervention group: They receive both usual treatments and foot bath (warm water at 42 C for 20 minutes and then kept warm for 5 minutes once a day for 7 days).  
**Category**  
Treatment - Other

### 2

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

## 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**

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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**

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**Position**

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1991953381

**Phone**

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**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](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**