

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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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