Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 oximetery

9

Description
Anxiety
Timepoint
Daily
Method of measurement
Beck questionnare

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
Roshanak Mokaberinejad
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
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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