

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Comparative evaluation of the efficacy of acupuncture and warm cupping on clinical manifestations of patients with COVID-19

#### Protocol summary

##### Study aim

Comparative evaluation of efficacy of warm cupping and acupuncture on clinical manifestations of patients with COVID-19

##### Design

Three-arm parallel groups randomized trial, with blinded outcome assessment, on 90 patients. Using RAS or Random Allocation Software, patients are divided into 3 groups: the intervention (cupping or acupuncture) groups and the control group.

##### Settings and conduct

90- COVID-19-patients would be studied in Shohadaye Pakdasht and Ziaieian hospitals. After applying the inclusion and exclusion criteria of the study and completing the informed consent form with random blockade are placed in one of the intervention and control groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients between 18 and 75 years of age with a probable diagnosis of COVID-19 based on the protocol of Iran. Exclusion criteria: comorbidity, pregnancy and lactation, history of allergies and any skin lesions in the area.

##### Intervention groups

Intervention group1: The standard treatment for COVID-19 + warm cupping of back of chest, Three times a day for 3-7 days. Intervention group2: The standard treatment for COVID-19 + acupuncture standard needling method, once a day for 3-7 days. Control group: Standard treatment of COVID-19 according to the protocol of the Ministry of Health of Iran.

##### Main outcome variables

Blood oxygen saturation; severity of cough, severity of dyspnea; severity of chest pain (non cardiac); severity of demand of oxygen therapy; Length of hospital stay.

#### General information

##### Reason for update

end of data collection

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201127049504N1**

Registration date: **2020-12-25, 1399/10/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-05-17, 1400/02/27**

Update count: **1**

##### Registration date

2020-12-25, 1399/10/05

##### Registrant information

##### Name

Reihane Alipour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3379 5119

##### Email address

ralipour@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-25, 1399/10/05

##### Expected recruitment end date

2021-07-04, 1400/04/13

##### Actual recruitment start date

2020-12-24, 1399/10/04

##### Actual recruitment end date

2021-03-24, 1400/01/04

##### Trial completion date

2021-03-24, 1400/01/04

##### Scientific title

Comparative evaluation of the efficacy of acupuncture and warm cupping on clinical manifestations of patients

with COVID-19

**Public title**  
Effect of acupuncture and warm cupping on clinical manifestations of COVID-19

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Patients who need hospitalization according to the guidelines of "National guidelines for the diagnosis and treatment of COVID-19" and for whom medical treatment has been initiated. And  $o_2$  saturation  $< 93\%$ . Or Chest CT-scan with COVID-19 pattern. Volunteer to join the trial and sign the informed consent form.  
**Exclusion criteria:**  
 Patients with complications of serious underlying diseases, such as coronary heart disease, chronic obstructive pulmonary disease, obstructive pulmonary disease, meningitis, encephalitis, cirrhosis. Coagulation disorder and platelets  $< 50,000$ . Probability of pulmonary embolism. Patients with respiratory failure who require mechanical ventilation. Pregnant or lactating women. History of allergies and any skin lesions in the area. Not be volunteer to join the trial and sign the informed consent form.

**Age**  
From **18 years** old to **75 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**  
 Target sample size: **90**  
 Actual sample size reached: **128**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
 Using RAS or Random Allocation Software, they are divided into three groups: intervention groups cupping (B) or acupuncture (A) and the control group (C). Randomization will be done based on Block Randomization with six blocks. Then, for random allocation, 15 blocks of 6 AABBC, AABCBC, AACBCB, ABCABC, BABCAC, ACBBAC will be prepared and placed in envelopes. In order of entry and hospitalization of patients, one of the envelopes was selected at random and based on the obtained block, 6 patients will be assigned to three groups.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
 This study is single blind. Researcher who completes questionnaire is blind. The person who evaluates the outcome is unaware of the grouping. Groups A and B and C are available to outcome assessor.

**Placebo**  
Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
 Ethics committee of Tehran University of Medical Sciences  
**Street address**  
 1th Floor, Medicine School, Poursina St, Qods St, Enghelab St.  
**City**  
 Tehran  
**Province**  
 Tehran  
**Postal code**  
 1417613151  
**Approval date**  
 2020-11-17, 1399/08/27  
**Ethics committee reference number**  
 IR.TUMS.MEDICINE.REC.1399.802

## Health conditions studied

**1**

**Description of health condition studied**  
COVID-19

**ICD-10 code**  
U07.1

**ICD-10 code description**  
COVID-19, virus identified

## Primary outcomes

**1**

**Description**  
Blood oxygen saturation

**Timepoint**  
Before intervention and 1,2,3,4,5,6,7 days after intervention

**Method of measurement**  
Pulse oximetry

## Secondary outcomes

**1**

**Description**  
Severity of cough

**Timepoint**  
Before intervention and 1,2,3,4,5,6,7 days after intervention

## Method of measurement

CTCAE version 5

## 2

### Description

Severity of dyspnea

### Timepoint

Before intervention and 1,2,3,4,5,6,7 days after intervention

### Method of measurement

CTCAE version 5

## 3

### Description

Chest pain (non cardiac)

### Timepoint

Before intervention and 1,2,3,4,5,6,7 days after intervention

### Method of measurement

CTCAE version 5

## 4

### Description

Need to oxygen therapy

### Timepoint

Before intervention and 1,2,3,4,5,6,7 days after intervention

### Method of measurement

CTCAE version 5

## 5

### Description

Duration of hospital stay

### Timepoint

Last day of hospitalization

### Method of measurement

Day

## Intervention groups

## 1

### Description

Intervention group1: standard treatment (based on the latest National Diagnostic and Treatment Protocol) + warm cupping: retained cupping 4 cm from each side of the T3 vertebrae for 1 minute, then moving cupping 4 cm from the spinous process of thoracic vertebrae for 5 minutes. Three times a day for 3-7 days (based on patient hospitalization) ; with a medium glass with a mouth diameter of 5 cm and a height of 8 cm, so the suction rate is between 10 and 15 mm.

### Category

Treatment - Other

## 2

### Description

Intervention group2: standard treatment (based on the

latest National Diagnostic and Treatment Protocol) + Acupuncture with standard needling method (without electrical stimulation), once a day for 20 minutes for 3-7 days (based on patient hospitalization). Acupuncture will be done with 25×20 mm needle on acupoints: Lu5, Lu7, LI4, LV3, Ren12, Ren17, ST36.

### Category

Treatment - Other

## 3

### Description

Control group: standard treatment (based on the latest National Diagnostic and Treatment Protocol)

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Ziaeian hospital

#### Full name of responsible person

Reihane Alipour

#### Street address

Qazvin St.

#### City

Tehran

#### Province

Tehran

#### Postal code

1366736511

#### Phone

+98 21 5517 6814

#### Email

ziaeian@tums.ac.ir

#### Web page address

<https://ziaeian.tums.ac.ir>

## 2

### Recruitment center

#### Name of recruitment center

Shohada Pakdasht

#### Full name of responsible person

Asma Asadi

#### Street address

18 km of Khavaran road

#### City

Pakdasht

#### Province

Tehran

#### Postal code

1111111111

#### Phone

+98 21 3644 2001

#### Email

shpmc@sbmu.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Amir Hooman Kazemi

**Street address**

Enghelab St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1417613151

**Phone**

+98 21 6640 5373

**Email**

okazi@tums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Reihane Alipour

**Position**

PhD candidate

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

School of Traditional Persian Medicine, Vafamanesh St, Heravi Sq.

**City**

Tehran

**Province**

Tehran

**Postal code**

1668753961

**Phone**

+98 21 2691 2137

**Email**

ralipour@razi.tums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Amir Hooman Kazemi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

School of Traditional Persian Medicine, Vafamanesh St, Heravi Sq.

**City**

Tehran

**Province**

Tehran

**Postal code**

1668753961

**Phone**

+98 21 2691 2137

**Email**

amirhoomank@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Reihane Alipour

**Position**

PhD candidate

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

School of Traditional Persian Medicine, Vafamanesh St, Heravi Sq.

**City**

Tehran

**Province**

Tehran

**Postal code**

1668753961

**Phone**

+98 21 2691 2137

**Email**

ralipour@razi.tums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is 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

Only part of the data such as information about the main outcome or the like can be shared.

### When the data will become available and for how long

After the publication of the article

### To whom data/document is available

All academic people

### Under which criteria data/document could be used

After the publication of the article and for other studies and therapeutic use.

### From where data/document is obtainable

The person responsible for general accountability

### What processes are involved for a request to access data/document

Communication with the person responsible for general accountability

### Comments