# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 Ziaeian 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**

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Iran (Islamic Republic of)

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**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 o2 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 AABBCC, AABCBC, AACBCB, ABCABC, BABCAC, ACBBCA 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.
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**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 theT3 vertebrae for 1 minute, then moving cupping 4 cm from the spinous process of thoracic vertebraes 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**
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**2**

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## Sponsors / Funding sources

**1**

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**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**
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## 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**