Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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

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 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.
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 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
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