

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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 Ziaeiian 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 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 AABBC, 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 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

Ziaieian hospital

Full name of responsible person

Reihane Alipour

Street address

Qazvin St.

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2

Recruitment center

Name of recruitment center

Shohada Pakdasht

Full name of responsible person

Asma Asadi

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Pakdasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Amir Hooman Kazemi

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Reihane Alipour

Position

PhD candidate

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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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