

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Apr 2021

### The effect of cupping (Persian Method) on clinical manifestations of patients with COVID-19

#### Protocol summary

##### Study aim

The effect of cupping (Persian Method) on clinical manifestations of patients with COVID-19

##### Design

Clinical trial with control group, with parallel groups, not blind, randomized, phase 2 on 68 patients. 68 packets containing codes 0001 to 0068 were used for randomization. Then, by selecting one and having the selected code and using the output table of Block randomization statistical software, it is determined which group the patient is in the intervention or control group.

##### Settings and conduct

Patients referring to "Imam Khomeini" Hospital in Sari, "Pakdasht Martyrs" Hospital in Tehran and "Ayatollah Khansari" Hospital in Arak will enter the study at the discretion of Corona. Then, 68 patients between the ages of 18 and 75 with a probable diagnosis of COVID-19 based on national protocol, after applying the inclusion and exclusion criteria of the study and completing the conscious 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 group: The standard treatment for COVID-19 + hot cupping is 4 cm (T4) on each side of the vertebrae, 4 cm from the spinus process (for 5 minutes with a medium glass with a mouth diameter of 7 cm and a height of 7-9 cm). So that the suction rate is between 10 and 15 mm.); Three times a day for 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, shortness of breath, length of hospital stay

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131129015584N3**

Registration date: **2020-05-20, 1399/02/31**

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

Last update: **2020-05-20, 1399/02/31**

Update count: **0**

##### Registration date

2020-05-20, 1399/02/31

##### Registrant information

##### Name

Assie Jokar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3324 3117

##### Email address

arezoo2003dr@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-04, 1399/02/15

##### Expected recruitment end date

2020-06-19, 1399/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of cupping (Persian Method) on clinical manifestations of patients with COVID-19

#### Public title

The effect of hot cupping on corona symptoms

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Probable diagnosis of COVID-19 based on national Iranian protocol

##### Exclusion criteria:

Existence of comorbidity Pregnancy and lactation history of Allergy There is any skin lesion in the area

#### Age

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

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: **68**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Before intervention, each patient selects one of the 68 envelopes that contain the codes 001 to 068, then by having the selected code and using the output table of Block randomization statistical software, it is determined the patient in which group: intervention or controls.

#### 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 Mazandaran University of Medical Sciences

##### Street address

Moallem square, Sari, Iran.

##### City

Sari

##### Province

Mazandaran

##### Postal code

۴۸۱۵۷۳۳۹۷۱

#### Approval date

2020-05-04, 1399/02/15

#### Ethics committee reference number

IR.MAZUMS.REC.1399.162

## 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

Blood oxygen saturation level

#### Timepoint

0,1,2,3,5,7 days after intervention

#### Method of measurement

Pulse oximetry

## Secondary outcomes

### 1

#### Description

degree of dyspnea

#### Timepoint

0,1,2,3,5,7 days after intervention

#### Method of measurement

Likert,s scale

### 2

#### Description

Duration of hospital stay

#### Timepoint

7days after intervention

#### Method of measurement

day

## Intervention groups

### 1

#### Description

Intervention group: The standard treatment for COVID-19 (Azithromycin daily + Kaletra \*2 BD) + hot cupping is 4 cm (T4) on each side of the vertebrae, 4 cm from the spinus process (for 5 minutes with a medium glass with a mouth diameter of 7 cm and a height of 7-9 cm). So that the suction rate is between 10 and 15 mm.); Three times a day for 7 days.

#### Category

Treatment - Other

## 2

### Description

Control group: Control group: Corona standard treatment based on the protocol of the Ministry of Health of Iran (Azithromycin daily + Kaletra \*2 BD).

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Dr Assie Jokar

**Street address**

Imam Khomeini Hospital of Sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816633131

**Phone**

+98 11 3335 0670

**Fax**

+98 11 3336 3754

**Email**

publicrel@mazums.ac.ir

**Web page address**

<https://imamhospital.mazums.ac.ir/page-NImamSariMain/fa/94/form/pld25046>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr Majid Saidi

**Street address**

Moallem square

**City**

Sari

**Province**

Mazandaran

**Postal code**

۴۸۱۵۷۳۳۹۷۱

**Phone**

+98 11 3325 7230

**Email**

pajhooheshi@mazums.ac.ir

**Web page address**

<https://pajhooheshi.mazums.ac.ir/page-NPajhooheshiMain/fa/2/form/pld47946>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Mazandaran University of Medical Sciences

**Proportion provided by this source**

80

**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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Assie Jokar

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Khazar Blvd.

**City**

Sari

**Province**

Mazandaran

**Postal code**

4814878787

**Phone**

+98 11 3324 3117

**Fax****Email**

a.jokar@mazums.ac.ir

**Web page address**

<https://scholar.google.com/citations?user=25VPUvWA-AAJ&hl=en>

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Assie Jokar

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Khazar Blvd.

**City**

Sari

**Province**

Mazandaran

**Postal code**

4814878787

**Phone**

+98 11 3324 3117

**Fax**

**Email**

a.jokar@mazums.ac.ir

**Web page address**

<https://scholar.google.com/citations?user=25VPUvwAAA&hl=en>

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Assie Jokar

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Khazar Blvd.

**City**

Sari

**Province**

Mazandaran

**Postal code**

4814878787

**Phone**

+98 11 3324 3117

**Fax**

**Email**

a.jokar@mazums.ac.ir

**Web page address**

<https://scholar.google.com/citations?user=25VPUvwAAA&hl=en>

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

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**

After the publication of the article, the results and how to perform the intervention will 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 scientific accountability

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

Communication with the person responsible for scientific accountability

**Comments**