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
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 squre, Sari, Iran.

City
Sari

Province
Mazandaran

Postal code
۱۷۹۳۳۷۵۱۸۴

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
7 days 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
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
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Mazandaran
Postal code
481663131
Phone
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Email
publicrel@mazums.ac.ir
Web page address
https://imamhospital.mazums.ac.ir/page-NImamSariMain/fa/94/form/pId25046

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 squre
City
Sari
Province
Mazandaran
Postal code
4814878787
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Fax
+98 11 3324 3117
Email
pajhoosh@mazums.ac.ir
Web page address
https://scholar.google.com/citations?user=25VPUvwAAAJ&hl=en
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
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Other areas of specialty/work
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https://scholar.google.com/citations?user=25VPUvwAAAJ&hl=en
**Person responsible for updating data**

**Contact**

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**Full name of responsible person**
Assie Jokar

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**Fax**

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a.jokar@mazums.ac.ir

**Web page address**

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**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**