Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evaluating the effect of topical combination galbanum oil and dry cupping therapy to alleviate COVID-19 patients symptoms

Protocol summary

Study aim

Evaluating the effect of topical combination galbanum oil and dry cupping therapy to alleviate COVID-19 patients symptoms

Design

Clinical trial with control group with parallel groups, without blinding, randomized, phase 3 on 60 patients. Block randomization is used for randomization.

Settings and conduct

Available standard treatment (according to the latest protocol of the Covid-19 headquarters) + Initially, 2 cc of galbanum oil is massaged in the back of the chest until the oil is absorbed into the skin + hot cupping behind the chest at a distance of 4 cm from the vertebral spines, fixed at point T4 for one minute and sliding on both sides of the spine to It is performed for 5 minutes, three times a day, at the time of hospitalization for 3- 5 days (from the first day of hospitalization to a maximum of 5 days of hospitalization). Hot cupping using a medium-sized balloon cup (cup opening width is 5 cm and cup height is 8 cm with a suction of about 10-15 mm). Place of study of Imam Khomeini Hospital Complex in Tehran

Participants/Inclusion and exclusion criteria

Patients aged 18-80 years with positive PCR test COVID-19 With inpatient clinical criteria (T>38°C or severe cough or shortness of breath or RR> 24 per min or O2 sat <93%) non-entry: pregnancy Breastfeeding,coagulopathy disease, vertebral fracture or herniated disc Hearth and renal failure

Intervention groups

The case group includes people who, in addition to standard treatment for coronavirus infectious disease, receive dry cupping and galbanum oil. The control group includes people who receive only standard treatment for coronavirus infectious disease.

Main outcome variables

The primary outcome involves a recovery period in which the patient is in a position to: fever <37.2 ° in the early morning or <37.8 during the day - number of breaths ≤ 24 in room air - O2sat> 94 in room air and lack of cough or mild cough.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201111049349N1**
Registration date: **2021-11-10, 1400/08/19**
Registration timing: **prospective**

Last update: **2021-11-10, 1400/08/19**
Update count: **0**

Registration date

2021-11-10, 1400/08/19

Registrant information

Name

Fatemeh Emadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 4055

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the effect of topical combination galbanum oil and dry cupping therapy to alleviate COVID-19 patients symptoms

Public title
Effect of dry cupping therapy and galbanum oil in treatment of coronavirus patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Positive PCR test From 18 to 80 years old (male and female) Clinical criteria for hospitalization (fever ≥ 38 °C- sever cough or shortness of breath or blood oxygen saturation≤ 93% or respiratory Rate ≥24 breaths/minute or positive CPR Completion of the informed consent form by the patient or his/her companions

Exclusion criteria:
Pregnancy or breastfeeding intubation Existence of any history of allergies and skin allergies to the consumption of any of the components of the herbal product Hearth failure renal failure Receive chemotherapy vertebral fracture or herniated disc Open wound at the site of cupping Inability and unwillingness of the patient to fill out a personal consent form to enter the study Coagulation disease Immune Deficiency Disease

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples will be randomly assigned to four blocks using Random Allocation Software. Blocking and allocation sequences for concealment will be done by the non-involved researcher (Allocation Concealment). The sample allocation ratio will be Allocation 1:1 and will be divided into two groups of receiving cupping and control group (Assignment). Then based on blocks and allocation sequences cupping therapy will be given to patients. This is an open-label study and blinding will not happen.

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 Shahed University

Street address
Tehran-Qom Highway, Opposite side of Imam Khomeini Holy Shrine, Tehran

City
Tehran

Province
Tehran

Postal code
3319118651

Approval date
2020-10-27, 1399/08/06

Ethics committee reference number
IR.SHAHED.REC.1399.108

Health conditions studied

1

Description of health condition studied
Coronavirus infection

ICD-10 code
B34.2

ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Percentage of blood oxygen saturation

Timepoint
Before the intervention and days 1,2,3,4,5 after the intervention

Method of measurement
Pulse oximeter device

Secondary outcomes

1

Description
Sevierty of cough

Timepoint
Before the intervention and days 1,2,3,4,5 after the intervention

Method of measurement
CTCAE version 5 (Common Terminology Criteriafor Adverse Events Version 5.0)

2

Description
Severe need for oxygen therapy
Timepoint
Before the intervention and days 1,2,3,4,5 after the intervention
Method of measurement
CTCAE version 5

3

Description
Sevierty of dyspnea
Timepoint
Before the intervention and days 1,2,3,4,5 after the intervention
Method of measurement
CTCAE version 5

4

Description
Sevierty of Chest pain (non-cardiac)
Timepoint
Before the intervention and days 1,2,3,4,5 after the intervention
Method of measurement
CTCAE version 5

Intervention groups

1

Description
Intervention group: The group which receive cupping therapy with galbanum oil application and standard medicines. Preparation of medicine:To prepare galbanum essential oil, galbanum gum is prepared from a suitable type of reputable herbal market and then, after the approval of a botanist, the voucher number is received from the herbarium of Faculty of Pharmacy, University of Tehran. Then, to prepare its essential oil, 200 g galbanum is poured into a balloon. Then, using water distillation method (hydrodistillation) and Clevenger apparatus, essential oil is extracted for 4 hours and the oil percentage is calculated (V/W). The water residue is removed by anhydrous sodium sulfate and the achieved oil is stored in a dark container in a refrigerator at 4-5°C prior to use in formulation or in hexane or petroleum ether solvent for essential oil components analysis by GC /MS.The achieved galbanum essential oil was then mixed with Almond violet oil (10%) (Tuba Green Gold Company) with the ratio of 5:95 and stir to make homogeneous formulation.
Category
Treatment - Drugs

2

Description
Control group: The control group will be received only the prescribed medications for the treatment of COVID-19 according to the protocol of the Ministry of Health.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Fateme Seydi
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1nd floor, No 43,Shahid Hajisadehi Avenue, Dardasht Avenue, Narmak
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Shahed University
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
Shahed University
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Fateme Seydi
Position
Phd student
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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
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is 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 publishing the article
To whom data/document is available
The results will be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
After the publication of the article for further and supplementary studies and clinical and therapeutic applications
From where data/document is obtainable
Responsible for public accountability
What processes are involved for a request to access data/document

Communicate with the public accountant	**Comments**