

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 ($T > 38^{\circ}\text{C}$ or severe cough or shortness of breath or $\text{RR} > 24$ per min or O_2 sat $< 93\%$) non-entry: pregnancy Breastfeeding, coagulopathy disease, vertebral fracture or herniated disc Heart 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 $< 37.2^{\circ}$ in the early morning or < 37.8 during the day - number of breaths \leq

24 in room air - $\text{O}_2\text{sat} > 94$ 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

fatemeh12emadi@yahoo.com

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 $\leq 93\%$ 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

Street address

1nd floor, No 43, Shahid Hajisadehi Avenue, Dardasht Avenue, Narmak

City

Tehran

Province

Tehran

Postal code

1651813911

Phone

+98 21 7793 8493

Email

fateme.seydi1444@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Maryam Iranzad asl

Street address

Tehran-Qom Highway Opposite side of Imam Khomeini Holy Shrine Tehran, Shahed University, Department of traditional medicine

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 4055

Email

m_iranzadasl@yahoo.com

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

m_iranzadasl@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Shahed University

Full name of responsible person

Fatemeh Seydi

Position

Ph.D Student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

1nd floor, No 43, Shahid Hajisadehi Avenue, Dardasht Avenue, Narmak

City

Tehran

Province

Tehran

Postal code

1651813911

Phone

+98 21 7793 8493

Email

fatemeh.seydi1444@gmail.com

Person responsible for general inquiries**Contact****Name of organization / entity**

Shahed University

Full name of responsible person

Fateme Seydi

Position

Phd student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

1nd floor, No 43, East Shahid Hajisadghi Avenue, Dardasht Avenue, Narma

City

Tehran

Province

Tehran

Postal code

1651813911

Phone

+98 21 7793 8493

Email

fateme.seydi1444@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahed University

Full name of responsible person

Maryam Iranzad Asl

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Tehran-Qom Highway Opposite side of Imam Khomeini Holy Shrine Tehran, Shahed University, Department of traditional medicine

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 4055

Email**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

