Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the effects of Shilajit (Momiai) with placebo on clinical course, severity indices, admission duration and mortality rate in patients with moderate Coronavirus disease 2019 (COVID-19): A triple - blind randomized controlled trial

Protocol summary

Study aim
Identifying effects of Shilajit (Mumiai) on clinical course and outcomes of COVID-19 disease

Design
Phase 3 parallel-group triple-blind randomized controlled trial on 110 patients. Randomization will be done using the permuted block randomization approach with variable sizes (2 and 4).

Settings and conduct
Study location: COVID ward of the Bohlool Gonabadi hospital, Gonabad city; Study population: All patients with a moderate form of COVID-19 disease who are refered to Allameh Bohlool Gonabadi Hospital. Type of blinding: Triple-blinded; Blinding process: Blinding will be performed using capsules with the same shape and color as the capsules in the intervention group. Therefore, patient, clinician, and enumerator will be blinded about the content of the capsules and type of treatment. Type of treatment will be determined as A and B for the analyst; therefore, he will be unaware of the nature of the treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosed moderate COVID-19 disease (based on the World Health organization laboratory and clinical criteria); Receiving standard medication for moderate disease based on COVID-19 management protocols; Age between 18 and 75 years old; Signing the informed consent form. Non-inclusion criteria: Pregnancy or lactation; Immune suppression conditions; History of chronic pulmonary diseases; Severe kidney failure, liver failure, heart failure; underlying diseases (diabetes and hypertension).

Intervention groups
Participants in the intervention group will receive two 500mg Shilajit capsules per day for 2 weeks and the control group will also receive placebo capsules for two weeks.

Main outcome variables
Clinical improvement up to 14 days after treatment; Cough; Headache; Sore throat; Chills; Smell disorder; Myalgia; Axillary Temperature; SPO2: FiO2 ratio.

General information

Reason for update
Updating the sampling actual date and actual sample size.

Acronym

IRCT registration information
IRCT registration number: **IRCT20210508051225N1**
Registration date: **2021-06-14, 1400/03/24**
Registration timing: **prospective**

Last update: **2026-01-06, 1404/10/16**
Update count: **1**

Registration date
2021-06-14, 1400/03/24

Registrant information

Name
Narjes Bahri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 5722 3028

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nargesbahri@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-22, 1401/03/01
Expected recruitment end date
2024-02-20, 1402/12/01
Actual recruitment start date
2022-03-08, 1400/12/17
Actual recruitment end date
2024-12-20, 1403/09/30
Trial completion date
2024-12-20, 1403/09/30

Scientific title
Comparison of the effects of Shilajit (Momiai) with placebo on clinical course, severity indices, admission duration and mortality rate in patients with moderate Coronavirus disease 2019 (COVID-19): A triple -blind randomized controlled trial

Public title
Effects of Shilajit (Momiai) on COVID-19 disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of moderate COVID-19 disease (based on the World Health Organization laboratory and clinical criteria) Receiving standard and routine medications for moderate COVID-19 based on management protocols for COVID-19 age between 18 and 75 years old signing the written informed consent form
Exclusion criteria:
Pregnancy Lactation Immune deficiency conditions (receiving chemotherapy, organ or bone marrow transplantation, autoimmune diseases) History of chronic pulmonary disease Participating or being registered for other trials Severe renal failure (GFR< 30ml/min) Liver failure Heart failure (EF<40%) History underlying diseases including diabetes and hypertension
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **110**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done using the permuted block randomization approach with variable sizes of 2 and 4. The analyzer will use online randomization website to generate the randomization list. The allocation randomization will also be concealed using opaque sealed envelopes with random sequences.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Capsules with shape and color similar to the intervention group capsules will be used for blinding. Patients, therapist physician, enumerator and statistician will be blinded regarding the content of the capsules. Type of treatment will be determined as A and B for the analyst; therefore, he will be unaware of the nature of the treatment.
Placebo
Used
Assignment
Parallel
Other design features
none

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Gonabad University of Medical Sciences
Street address
Gonabad University of Medical Sciences, Imam Khomeini St., Gonabad, Khorasan Razavi
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Province
Razavi Khorasan
Postal code
9691793718
Approval date
2021-05-03, 1400/02/13
Ethics committee reference number
IR.GMU.REC.1400.012

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
Severity of clinical presentations of COVID-19
Timepoint
At the beginning of the study (before intervention initiation) and 7, 14, and 28 days after Shilajit use

Method of measurement
The criteria proposed by the World Health Organization will be used to determine COVID-19 severity and to assess the changes in disease severity during the study. Based on the criteria disease severity is defined based on a score between 0 and 8 as follows: (0) no clinical or virologic sign of infection (1) no limitation in activity (2) limitation in activity (3) hospital admission without oxygen therapy (4) hospital admission with oxygen therapy with mask or nasal cannula (5) hospital admission with non-invasive oxygen therapy or high flow oxygen (6) hospital admission with intubation or mechanical ventilation (7) hospital admission with supported ventilation including extracorporeal membrane oxygenation, vasopressors, or renal replacement therapy (8) death

2

Description
Oxygen saturation:fraction of inspired oxygen ratio (SPO2:FiO2)
Timepoint
At the beginning of the study (before intervention initiation) and 7, 14, and 28 days after Shilajit use
Method of measurement
Pulse oxymeter

3

Description
Axillary temperature
Timepoint
At the beginning of the study (before intervention initiation) and daily afterwards
Method of measurement
mercury thermometer

4

Description
Incidence of respiratory distress
Timepoint
At the beginning of the study (before intervention initiation) and anytime during the study period
Method of measurement
Patient records data/Physician examination

5

Description
Ventilation need
Timepoint
At the beginning of the study (before intervention initiation) and anytime during the study period
Method of measurement
Patient records data/Physician examination

6

Description
Intensive Care Unit admission
Timepoint
At the beginning of the study (before intervention initiation) and anytime during the study period
Method of measurement
Patient records data/Physician examination

7

Description
Duration of Intensive Care Unit admission
Timepoint
anytime during the study period
Method of measurement
Patient records data/Physician examination

8

Description
Time of death
Timepoint
anytime during the study period
Method of measurement
Patient records data/Physician examination

9

Description
Respiratory rate
Timepoint
At the beginning of the study (before intervention initiation) and daily afterwards
Method of measurement
Patient records data/Physician examination

Secondary outcomes

1

Description
All-cause mortality
Timepoint
any time during the study period
Method of measurement
Incidence of death due to any cause during the study period

2

Description
Hospital admission duration
Timepoint
during the study period
Method of measurement
Days from admission to discharge or decease

3

Description
Intensive Care Unit admission duration
Timepoint
during the study period
Method of measurement
Days from admission in the Intensive care unit to discharge or decease

4

Description
Intensive Care Unit admission
Timepoint
During the study period
Method of measurement
Incidence of Intensive Care Unit admission

5

Description
Time to Intensive Care Unit admission
Timepoint
During the study period
Method of measurement
Days from hospital admission to Intensive Care Unit referral

6

Description
Ventilation requirement
Timepoint
During the study period
Method of measurement
Incidence of ventilation requirement

7

Description
Time to ventilation
Timepoint
During the study period
Method of measurement
Days from admission to initiation of mechanical ventilation

Intervention groups

1

Description
Intervention group: The intervention group will receive two 500mg Shilajit capsules per day for two weeks. Intervention group will also receive medical treatments based on moderate COVID-19 treatment protocols.
Category
Treatment - Drugs

2

Description
Control group: The control group will receive two placebo capsules per day for two weeks. Control group will also receive medical treatments based on moderate COVID-19 treatment protocols.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Bohllol Hospital
Full name of responsible person
Narjes Bahri
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
A-10-1269-11
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Narjes Bahri
Position
Assisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
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Person responsible for updating data

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available