Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The effects of Trehala Manna (Shekar Tighal) on inflammatory and biochemistry biomarkers, and clinical outcomes in Covid-19 patients; A randomized double-blind placebo-controlled trial

Protocol summary

Study aim
The effect of Trehala Manna on inflammatory biomarkers and clinical symptoms in covid-19 patients.

Design
A double blinded, parallel, randomized controlled clinical trial

Settings and conduct
Generation of the allocation sequence will be implemented by second investigator of study and enrollment of participants, and assignment of participants to intervention or control group will be done by the first investigator. This study will be implemented in Imam Reza Hospital (501AJA). Researcher, patients and data analysts will be blinded.

Participants/Inclusion and exclusion criteria
Age between 18-65 Written informed consent Covid-19 patients (PCR positive test or clinical symptoms such as fever > 38, respiratory rate ≥ 24, dry cough, myalgia, asthenia, anosmia, and or anorexia Admission to general corvid-19 unit in hospital Patients who estimate that reside in hospital at least 7 days. Non ICU patients

Intervention groups
Intervention: 2 sachets of Trehala Manna q12h (two times/day) Placebo: 2 sachets of Maltodextrin q12h (two times/day)

Main outcome variables
C- reactive protein as an inflammatory biomarker

General information

Reason for update
The change in the spread of the COVID-19 disease following the waves of the pandemic caused a change in the expected date for the start of patient recruitment, and the study was carried out a few months after registration.

Acronym

IRCT registration information
IRCT registration number: **IRCT20211029052904N1**
Registration date: **2021-12-30, 1400/10/09**
Registration timing: **prospective**

Last update: **2023-12-20, 1402/09/29**
Update count: **2**

Registration date
2021-12-30, 1400/10/09

Registrant information

Name
Mahdi Keshani
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 31 3227 6277
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mkeshani@nutr.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-06, 1400/09/15

Expected recruitment end date
2022-02-04, 1400/11/15

Actual recruitment start date
2022-05-01, 1401/02/11

Actual recruitment end date
2022-10-03, 1401/07/11

Trial completion date
2022-10-03, 1401/07/11

Scientific title
The effects of Trehala Manna (Shekar Tighal) on inflammatory and biochemistry biomarkers, and clinical

outcomes in Covid-19 patients; A randomized double-blind placebo-controlled trial

Public title
The effects of Skekar Tighal on covid-19
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-65 Written informed consent Covid-19 patients (PCR positive test or clinical symptoms such as fever > 38, respiratory rate ≥ 24, dry cough, myalgia, asthenia, anosmia, and or anorexia Admission to general corvid-19 unit in hospital Patients who estimate that reside in hospital at least 7 days. Non ICU patients
Exclusion criteria:
Did not write informed consent Pregnancy and lactation Smoking Usage of other herbal medicine Hypertension (definition by ACC/AHA SBP/DBP ≥ 130/80)
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Each patient will be recruited into intervention or control group using a valid random number making website: https://www.sealedenvelope.com/simple-randomiser/v1/lists. Eligible patients will be randomly allocated in a ratio of 1:1 to receive intervention or placebo with a block size of four.
Blinding (investigator's opinion)
Double blinded
Blinding description
The sealed and opaque envelopes prepared by a blinded herbal pharmacologist along with similar sachets that only varied in label (A or B) containing Trehala Manna or placebo. These are provided to the first investigator without specifying which package is the intervention or the placebo. The content of envelope determines A or B. After implementing statistical analysis, we will open envelopes to reveal labels.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of AJA University of Medical Sciences
Street address
West Fatemi Ave, Etemadzadeh Ave
City
Tehran
Province
Tehran
Postal code
1411718541
Approval date
2021-12-22, 1400/10/01
Ethics committee reference number
IR.AJAUMS.REC.1400.253

Health conditions studied

1

Description of health condition studied
Covid-19
ICD-10 code
J12.81
ICD-10 code description
Pneumonia due to SARS-associated coronavirus

Primary outcomes

1

Description
C reactive protein
Timepoint
At baseline (day 0) and end of the study (day 8)
Method of measurement
ELISA commercial diagnostic kit

2

Description
Assess the severity of cough
Timepoint
At baseline (day 0) and end of the study (day 8)
Method of measurement
Visual Analogue Scale

3

Description
Alanine transaminase
Timepoint
At baseline (day 0) and end of the study (day 8)

Method of measurement
Spectrophotometry

4

Description
Aspartate transaminase
Timepoint
At baseline (day 0) and end of the study (day 8)
Method of measurement
Spectrophotometry

Secondary outcomes

1

Description
Hospitalization days
Timepoint
Continuous
Method of measurement
Discharge day minus first day

Intervention groups

1

Description
Intervention group: 2 sachets of Trehala manna (refined Shekar Tighal) daily, 5 grams per sachet (a total of 10 grams per day in the form of a drink solution) for 7 days. In addition to the usual treatment protocols for patients.
Category
Treatment - Other

2

Description
Control group: 2 sachets of Maltodextrin daily (each sachet contains 5 grams and a total of 10 grams as a drink solution). In addition to the usual treatment protocols for patients.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Mahdi keshani
Street address
Fatemi St. West, Shahid Etemadzadeh St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mojtaba Yousefi Zoshk
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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
Artesh 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
Artesh University of Medical Sciences
Full name of responsible person
Mahdi keshani
Position
MSC student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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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
Yes - There is 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
Information about the study will be published after the nonidentifying individuals and when the project is completed.
When the data will become available and for how long
6 months after final manuscript
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
For further analysis
From where data/document is obtainable
Mahdi keshani Mahdikeshani1@yahoo.com
What processes are involved for a request to access data/document
After reviewing the request and full transparency about the purposes of using the data, the data will be provided.
Comments