

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 covid-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)

Phone

+98 31 3227 6277

Email address

mkesani@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 $\geq$ 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 $\geq$ 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

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

jps@ajaums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Mojtaba Yousefi Zoshk

Street address

West Fatemi St, Shahid Etemadzadeh St

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 4382 2449

Email

jps@ajaums.ac.ir

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

Nutrition

Street address

West Fatemi St, Shahid etemadzadeh St

City

Tehran

Province
Tehran
Postal code
1411718541
Phone
+98 21 4382 2449
Email
mahdikeshani1@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
SeyedMahdi Mirghazanfari
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
West Fatemi St, Shahid etemadzadeh St
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
smmirghazanfari@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
mahdi keshani
Position
MCS student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition

Street address
Dr. fatemi
City
tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 4382 2449
Email
mkeshani87@yahoo.com

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