Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of the effect of Kefir produced from cow's milk on the clinical outcomes and immune response of patients with COVID-19; a randomized clinical trial

Protocol summary

Study aim
The goal of this study was to determine the effect of Kefir supplementation of on clinical outcomes and immune response in COVID-19 patients.

Design
A double-blind randomized controlled clinical trial with a sample size of 100 patients

Settings and conduct
In this study, 100 adult patients with the criteria of being infected with COVID-19 after being admitted to the Corona Ward of Tehran Army Hospital 503 were selected based on the entry criteria and randomly entered into 2 study groups.

Participants/Inclusion and exclusion criteria
Hospitalized patients diagnosed with COVID-19

Intervention groups
In the intervention group, participants received kefir grains (2-10%) to milk twice a day (250 ccs each time) for two weeks.

Main outcome variables
Inflammatory factors and clinical status

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221106056423N1**
Registration date: **2022-11-27, 1401/09/06**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-27, 1401/09/06**
Update count: **0**

Registration date
2022-11-27, 1401/09/06

Registrant information

Name
Ramin Gooruee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4382 2952

Email address
ramingooruee@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-22, 1401/09/01

Expected recruitment end date
2022-12-06, 1401/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Kefir produced from cow's milk on the clinical outcomes and immune response of patients with COVID-19; a randomized clinical trial

Public title
Evaluation of the effect of Kefir produced from cow's milk on the treatment process and immune response of patients with Corona virus 2019 (COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Positive PCR-test confirming COVID-19 infection Having a moderate or severe level of the disease ICU patients

(provided that there is no restriction on the consumption of certain food substances) Age between 20-60 years Administering 2 doses of Sinopharm vaccine Absence of food allergies

Exclusion criteria:

Pregnancy or lactating Use of anti-coagulant drugs No infection with the Covid-19 virus

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

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 St. - Shahid Etemadzadeh St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2021-12-22, 1400/10/01

Ethics committee reference number

IR.AJAUMS.REC.1400.252

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Fever

Timepoint

At the baseline and end of the intervention

Method of measurement

Thermometer

2

Description

C-Reactive Protein

Timepoint

At the baseline and end of the intervention

Method of measurement

kit (Bionik, Iran) with the BT3500 (Biotecnica Instruments SpA -Italy) auto-analyzer

3

Description

Erythrocyte Sedimentation Rate (ESR)

Timepoint

At the baseline and end of the intervention

Method of measurement

Westergren Method

4

Description

Dyspnea

Timepoint

At the baseline and end of the intervention

Method of measurement

Clinical examintation

Secondary outcomes

1

Description

Gastrointestinal symptoms

Timepoint

At the baseline and the end of the intervention

Method of measurement

Clinical examination

2

Description

WBC

Timepoint

At the baseline and the end of the intervention

Method of measurement

Sysmex K-1000 Hematology Analyzer

Intervention groups

1

Description
Intervention group: Giving 250 cc of kefir (twice a day) along with following the hospital diet for 14 days.
Category
Treatment - Other

2

Description
Control group: No intervention with kefir and only following the hospital diet for 14 days.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Faezeh Bani Yaghubi
Street address
501 Army Hospital, above the Embassy of Pakistan, Etamadzadeh St., Fatemi West St., Tehran
City
Tehran
Province
Tehran
Postal code
1415613120
Phone
+98 21 8609 6350
Email
committe.aja@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Saeid Hadi
Street address
Tehran - West Fatemi St. - Shahid Etemadzadeh St
City
Tehran
Province
Tehran
Postal code
1415613121
Phone
+98 21 8609 6350
Email
committe.aja@gmail.com
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
Ramin Gooruee
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
دانشگاه علوم پزشکی آجا
City
Tehran
Province
Tehran
Postal code
1415613121
Phone
+98 21 4382 2952
Fax
Email
ramingooruee@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Ramin Gooruee
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Nutrition

Street address
Artesh University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1415613121
Phone
+98 21 4382 2952
Fax
Email
ramingooruee@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Ramin Gooruee
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Artesh University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1415613121
Phone
+98 21 4382 2952
Fax
Email
ramingooruee@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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