

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 (Biotechnica 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 examination

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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Saeid Hadi

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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

Ramin Gooruee

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Position

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Latest degree

Master

Other areas of specialty/work

Nutrition

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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