

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of the effect of dairy product donkey milk on the course of signs of patients with suspected corona disease (COVID-19)

Protocol summary

Study aim

Determining Effect of Dairy Product of Donkey milk on the Clinical Course of Symptoms of COVID_19 Outpatients

Design

Randomized clinical trial with parallel intervention and control groups

Settings and conduct

Patients with mild to moderate illness are candidates for quarantine and receiving this treatment at home after a visit to the clinics designated by the Department of Health for COVID-19

Participants/Inclusion and exclusion criteria

Patients with COVID-19 with mild to moderate severity according to the protocol of the Ministry of Health, are candidates for outpatient treatment; aged 18-65 years. Patients with allergies and asthma, hypertension, diabetes, pregnancy / lactation, heart failure, chronic renal failure, undergoing chemotherapy, receiving corticosteroids and having a defective immune system are not included in the study.

Intervention groups

Intervention group: receiving medicine for the treatment of COVID-19 according to the protocol of the Ministry of Health along with receiving dairy product of Donkey milk. Control group: receiving medicine for the treatment of COVID-19 according to the protocol of the Ministry of Health.

Main outcome variables

Clinical status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161108030776N3**

Registration date: **2020-08-26, 1399/06/05**

Registration timing: **prospective**

Last update: **2020-08-26, 1399/06/05**

Update count: **0**

Registration date

2020-08-26, 1399/06/05

Registrant information

Name

Mohadese Kamali

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

mohadesekamali0912@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-05, 1399/06/15

Expected recruitment end date

2020-10-06, 1399/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of dairy product donkey milk on the course of signs of patients with suspected corona disease (COVID-19)

Public title

Effect of donkey milk on the new corona virus infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with COVID-19 Mild to moderate disease
Candidates for outpatient treatment based on the protocol of the Ministry of Health Patients 18-65 years old

Exclusion criteria:

Patients with allergies and asthma Patients with hypertension Patients with diabetes Pregnancy / lactation Patients with heart failure Patients with chronic renal failure Patients undergoing chemotherapy Patients receiving corticosteroids Patients with immunodeficiency

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

First, according to the inclusion criteria, patients are selected and then according to the random sequence obtained through random allocation software, in the same random order, patients will be divided into two groups of test and control.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Kerman University of Medical Sciences

Street address

campus of University of Medical Sciences, the beginning of Haft Bagh Alavi axis

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2020-08-15, 1399/05/25

Ethics committee reference number

IR.KMU.REC.1399.321

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes**1****Description**

Body temperature

Timepoint

Days 0-1-2-3-4-7-14 after the start of the intervention

Method of measurement

Mercury thermometer

2**Description**

Cough (severity-frequency)

Timepoint

Days 0-1-2-3-4-7-14 after the start of the intervention

Method of measurement

Fiston Scale

3**Description**

Weakness and lethargy

Timepoint

Days 0-1-2-3-4-7-14 after the start of the intervention

Method of measurement

Visual analog scale (VAS)

4**Description**

Body pain

Timepoint

Days 0-1-2-3-4-7-14 after the start of the intervention

Method of measurement

Visual analog scale (VAS)

5**Description**

Breathing speed

Timepoint

Days 0-1-2-3-4-7-14 after the start of the intervention

Method of measurement

Count the number of breaths per minute

6**Description**

Diarrhea (watery stools)

Timepoint

Days 0-1-2-3-4-7-14 after the start of the intervention

Method of measurement

Question from the patient

Secondary outcomes

1

Description

Being admitted to the hospital

Timepoint

Days 0-1-2-3-4-7-14 after the start of the intervention

Method of measurement

The ratio of the number of cases leading to hospitalization to the total number of patients in each group

2

Description

Death rate

Timepoint

Days 0-1-2-3-4-7-14 after the start of the intervention

Method of measurement

Ratio of number of deaths to total patients in each group

Intervention groups

1

Description

Intervention group: In addition to drug treatment according to the protocol of the Ministry of Health, patients in this group receive donkey milk at a rate of 300 cc daily with 5 grams of candy for 5 days.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group receive medication according to the protocol of the Ministry of Health.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

Haleh Tajadini

Street address

Afzalipour hospital, next to Bahonar University, Imam Highway

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dr_haleh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Deputy of Research and Technology, beginning of Ibn Sina Street, Somayeh Intersection (Tahmasb Abad)

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Phone

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Fax

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Email

abpardakhty@kmu.ac.ir

Web page address

<http://vresearch.kmu.ac.ir/fa>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Haleh Tajadini

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Haleh tajadini

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Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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dr_haleh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mohadese Kamali

Position

Associate professor

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 on the main outcome will be published after the end of the study.

When the data will become available and for how long

Immediately after publishing the article

To whom data/document is available

All researchers

Under which criteria data/document could be used

The data and results can be used by all researchers for research in the fields related to this study.

From where data/document is obtainable

Haleh Tajadini; dr_haleh@yahoo.com Mohadese Kamali; mohadesekamali0912@gmail.com

What processes are involved for a request to access data/document

The data will be provided to the applicant within one month after reviewing and confirming the application.

Comments