Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Iran (Islamic Republic of)

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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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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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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

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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 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