Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effectiveness of COVID-19 specific antibody in hyper-immune bovine milk & colostrum with ordinary bovine milk & colostrum on reducing the need for hospitalization and improving clinical symptoms of patients with COVID-19 that are taken care of in home.

Protocol summary

Study aim

Comparison of the Effectiveness of COVID-19specific antibody in hyperimmune bovine milk&colostrum with ordinary bovine milk&colostrum on reducing the need for hospitalization and improving clinical symptoms of patients,referred to AlzahraHospital in Isfahan that are taken care of in home.

Design

Double blinded placebo control randomized clinical trial of 600 patients. A random number table is used for randomization.

Settings and conduct

Current study is double blinded, randomized. In that patients of COVID-19diagnosis by PCR test refereed to the COVID-19test clinics based on the random number table are divided in two groups. After explaining the study and receiving consent form one group is given 150cc of hyperimmune milk twice a day morning and evening and the other group is given 150cc of ordinary milk twice daily.Milk packs are named as milkB and milkA. Executives, patients and distributor are not informed of the milks qualities.

Participants/Inclusion and exclusion criteria

Inclusion Criteria:patients of COVID-19 with positivepolymerase chain reaction (PCR) test;Lack of hospitalization indication;Oxygen Saturaion more than93%;RespiratoryRate more than24;Age more than18years old;signing of consent form;A maximum of 10days have elapsed since the onset of symptoms.Exclusion Criteria:Patients with immunodeficiency based on biography;Lactose intolerance;Uncontrollable vomit;Using antiviral drugs; Pregnancy;Failure to fill the consent form;Receiving immunosuppressive drugs.

Intervention groups

Effectiveness of hyperimmune bovine milk and colostrum will be orally tested on a group of referral COVID-19 patients to PCR test centers and a group of these patients is determined as control group that will be given normal bovine milk and colostrum.

Main outcome variables

Existence and lack of clinical symptoms such as fever,cough,shortness of breath and no hospitalization need.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200927048849N3**
Registration date: **2021-03-17, 1399/12/27**
Registration timing: **prospective**

Last update: **2021-03-17, 1399/12/27**
Update count: **0**

Registration date

2021-03-17, 1399/12/27

Registrant information

Name
Hassan Niliahmadabadi
Name of organization / entity
Virus research center of isfahan university
Country
Iran (Islamic Republic of)
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+98 31 3261 6334
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-03-20, 1399/12/30
Expected recruitment end date
2021-05-20, 1400/02/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of COVID-19 specific antibody in hyper-immune bovine milk & colostrum with ordinary bovine milk & colostrum on reducing the need for hospitalization and improving clinical symptoms of patients with COVID-19 that are taken care of in home.

Public title
Effect of hyperimmune bovine milk & colostrum in the healing process of COVID-19 patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infected patients of COVID-19 based on positive Polymerase Chain Reaction test Lack of hospitalization indication based on country protocol O2 Saturation more than 93% on the first visit Respiratory rate more than 24 on the first visit Age more than 18 years old Filling and signing of consent form A maximum of 10 days have elapsed since the onset of disease symptoms
Exclusion criteria:
Patients with immunodeficiency based on biography Lactose intolerance based on biography Uncontrollable vomiting Using antiviral drugs Pregnancy Failure to fill out the consent form Receiving immunosuppressive drugs
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **600**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients list with positive PCR is received through health center daily and numbered. Participants of the study are divided in two groups Using a simple randomization method using a table of random numbers and according to the entry and exit criteria. Such that the patients with even number are given hyperimmune milk and patients with odd number are given ordinary milk.
Blinding (investigator's opinion)
Double blinded
Blinding description
Referral patients to clinic with COVID-19 diagnosis by positive PCR from Nazopharynx are divided in two groups using a simple randomization method using a table of random numbers. Milks have two types hyperimmune and ordinary that are named as A and B on the top but their packaging are quite the same. One group is given milk A (ordinary or placebo) and the other group is given milk B or hyperimmune milk. The doctor, patient and distributor are not informed of the milks differences.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Deputy of research and technology, Building No. 4, Isfahan University of Medical Sciences, Hezar Jerib Ave., Azadi Sq.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-02-21, 1399/12/03
Ethics committee reference number
IR.MUI.MED.REC.1399.1029

Health conditions studied

1

Description of health condition studied
Covid-19 viral pneumonia
ICD-10 code
J12.81
ICD-10 code description
Pneumonia due to SARS-associated coronavirus

Primary outcomes

1

Description
Need of Hospitalization during the next 14 days
Timepoint

14 days after using the milk

Method of measurement

By phone call

2

Description

Need to go to the emergency room during 14 days

Timepoint

14 days after using the milk

Method of measurement

By phone call

3

Description

No fever and appearance of it

Timepoint

In days of 3, 5, 7, 10 and 14 after beginning the treatment

Method of measurement

By phone call

4

Description

No cough and appearance of it

Timepoint

In days of 3, 5, 7, 10 and 14 after beginning the treatment

Method of measurement

By phone call

5

Description

No shortness of breath and appearance of it

Timepoint

In days of 3, 5, 7, 10, 14 after beginning the treatment

Method of measurement

By phone call

6

Description

No muscular pain and appearance of it

Timepoint

In days of 3, 5, 7, 10, 14 after beginning the treatment

Method of measurement

By phone call

7

Description

Mortality rate during 28 days after beginning of the disease

Timepoint

28 days after beginning of disease

Method of measurement

By phone call

8

Description

ICU need during 28 days after beginning the disease

Timepoint

28 days after beginning of disease

Method of measurement

By phone call

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Referred COVID-19 patients to clinic of Alzahra hospital after explaining the study and obtaining consent the will be given twice a day, morning and evening 150 cc of vaccined cow's milk by COVID-19 virus antigen (hyperimmune milk)..

Category

Treatment - Drugs

2

Description

Control group: Referred Covid-19 patients to clinic of Alzahra hospital in Isfahan after explaining the study and obtaining consent form will be given twice a day, morning and evening 150 cc of ordinary bovine milk (placebo milk).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Health and Health Center of the state

Full name of responsible person

Reza Fadae

Street address

Health Department Province, Ebn E Sina Ave.

City

Isfahan

Province

Isfehan

Postal code

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Phone

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Fax

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Email

Health@mui.ac.ir

Web page address

https://phc.mui.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan university
Full name of responsible person
Rasoul Roknizadeh
Street address
Hezar Jerib Street
City
Isfahan
Province
Isfehan
Postal code
۸۱۷۴۶۷۳۴۴۱
Phone
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Fax
+98 31 3793 2170
Email
research.deputy@dean.ui.ac.ir
Web page address
https://ui.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan Oil Refinery
Proportion provided by this source
20
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

2

Sponsor
Name of organization / entity
Zeitoon Isfahan Vaccine Innovators Company
Full name of responsible person
Hassan Nili Ahmadabadi
Street address
Parvin Street
City
Isfahan
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Phone
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Fax
+98 31 3559 1833
Email
zeitoonisfahan@yahoo.com
Web page address
http://www.zeitoonisfahan.com/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zeitoon Isfahan Vaccine Innovators Company
Proportion provided by this source
50
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

3

Sponsor
Name of organization / entity
Biotechnology Investment Support Fund
Full name of responsible person
Mehdi deylam salehi
Street address
No. 6, East Saeb Tabrizi Ave., North Shirazi Ave., Molasadra Ave.
City
Tehran
Province
Tehran
Postal code
1991734385
Phone
+98 21 8803 3910
Fax
+98 21 8803 3910
Email
info@biotechfund.ir
Web page address
http://biotechfund.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Biotechnology Investment Support Fund
Proportion provided by this source
30
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

Virus research center of Isfahan university

Full name of responsible person

Hassan Niliahmadabadi

Position

Retired full professor of shiraz university and virology consultant and deputy of the virus research

Latest degree

Subspecialist

Other areas of specialty/work

Virology

Street address

No. 5 apartment unit, Parmisa building, alley No. 5, Mehrabad avenue, Mehrabad neighbourhood

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Virus research center of isfahan university

Full name of responsible person

Hassan Niliahmadabadi

Position

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Person responsible for updating data

Contact

Name of organization / entity

Virus research center of isfahan university

Full name of responsible person

Hassan Niliahmadabadi

Position

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Postal code

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Phone

+98 31 3261 6334

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

No - There is not 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