Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effectiveness of COVID-19 specific antibody in hyperimmune bovine milk & colostrum with ordinary bovine milk & colostrum in improving clinical symptoms and laboratory parameters and outcomes of patients with COVID-19 admitted to Hospital

Protocol summary

Study aim

Comparison of the Effectiveness of Covid-19 specific antibody in hyperimmune bovine milk & colostrum with ordinary milk & colostrum in improving clinical symptoms and laboratory parameters and outcomes of Covid-19 hospitalized patients

Design

Double blind placebo control randomized clinical trial of 40patients. A random number table is used for randomization

Settings and conduct

In first phase of clinical trial hyperimmune bovine milk is given to 40healthy men. If after 14days they hadn't shown upper infection rate compared with ordinary people the trial goes to next phase. In that hyperimmune colostrum and milk is given to 40hospitalized patients of Alzahra-hospital once a day for 5days and vital symptoms and experimental factors are assessed. Current study is double blinded, randomized. In that hospitalized patients of Covid- 19 diagnosis based on the random number table are divided in two groups. Intervention group is given 100cc of hyperimmune milk as an evening meal and control group is given 100cc of ordinary milk. Milk packs are named as milkA (hyperimmune) and milkB (ordinary). The doctor, patients and distributor are not informed of the milks qualities.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Infected Covid- 19 patients with positive PCR result; Hospitalization; With oxygen via nasal cannula O2sat more than 92%; O2 Sat more than 93%; Age more than18; Filling and signing of consent form; Allowing the patient to consume food orally Exclusion Criteria: Immunodeficiency; Lactose intolerance ; Uncontrollable vomit based on biography

Intervention groups

Hyperimmune colostrum and milk will be orally tested on hospitalized noncritical patients of Covid- 19 selected by random sampling and a group determined as control group is given ordinary colostrum and milk.

Main outcome variables

Length of hospital stay of experimental group compared with control group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200927048849N2**
Registration date: **2021-01-06, 1399/10/17**
Registration timing: **retrospective**

Last update: **2021-01-06, 1399/10/17**
Update count: **0**

Registration date

2021-01-06, 1399/10/17

Registrant information

Name

Hassan Niliahmadabadi

Name of organization / entity

Virus research center of isfahan university

Country

Iran (Islamic Republic of)

Phone

+98 31 3261 6334

Email address

nili@shirazu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-11-27, 1399/09/07
Expected recruitment end date
2020-12-20, 1399/09/30
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 hyperimmune bovine milk & colostrum with ordinary bovine milk & colostrum in improving clinical symptoms and laboratory parameters and outcomes of patients with COVID-19 admitted to Hospital

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 PCR or HRCT result compatible with disease Hospitalization of patient in hospital With oxygen via nasal cannula 93%≤O2 Sat Age >18years old Filling and signing of consent form Allowing the patient to consume food orally
Exclusion criteria:
Patients with immunodeficiency based on biography Patients with Lactose intolerance based on biography Uncontrollable vomit
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Current study is a double blinded randomized clinical trial. Randomization will be done as simple randomization by using random number table. Hospitalized patients of Alzahra hospital of Isfahan with COVID-19 diagnosis will be divided in two groups by using of random number table. After explaining the study and obtaining consent intervention group will be given daily 100 cc of milk of vaccinated cow with antigen of COVID-19 virus as an evening meal. After explaining the study and obtaining consent control group will be given 100 cc of unvaccinated cow's milk. Milk packs are named as Milk A and Milk B . The doctor, patient and distributor of milk do not know about the quality of the milks. Only the factory that pasteurizes is informed of the quality of milks and in the factory milk packs are labeled as A or B.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients will be divided in two groups by using of random number table. After explaining the study and obtaining consent of patients intervention group will be given 100 cc of hyper immune milk daily as an evening meal. Control group will be given 100 cc of ordinary milk after explaining the study and obtaining consent. Milk packs are named as Milk A and Milk B. The doctor, patient and distributor of milk are not informed of the quality of the milks.
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
Hezar Jerib Street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-11-06, 1399/08/16
Ethics committee reference number
IR.MUI.MED.REC.1399.672

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Hospital mortality rate
Timepoint
Daily from intervention
Method of measurement
Physician approval

2

Description
Mortality rate during 28 days after the beginning of disease
Timepoint
Daily from intervention
Method of measurement
Physician approval during admission and via tell contact after discharge

3

Description
Admission rate of patient in ICU (based on hospital protocols)
Timepoint
Daily from intervention
Method of measurement
Refer to the patient's file

4

Description
Days that patient needs to be hospitalized
Timepoint
Daily from intervention
Method of measurement
Refer to the patient's file

Secondary outcomes

1

Description
O2 Saturation
Timepoint
Measuring in the first day and days 3 and 5 or in the day of discharge
Method of measurement
Pulseoximetry

2

Description
Improvement rate of clinical symptoms such as dyspnea and fever
Timepoint
Measuring in the first day and days of 3 and 5 or in the day of discharge
Method of measurement
Data gathering sheet

3

Description
Erythrocytes sedimentation rate
Timepoint
Measuring in the first day and days of 3 and 5 or in the day of discharge
Method of measurement
Blood test via wester green method

4

Description
C-Reactive protein
Timepoint
Measuring in the first day and days of 3 and 5 or in the day of discharge
Method of measurement
Blood test

5

Description
Lymphocytopenia
Timepoint
Measuring in the first day and days of 3 and 5 or in the day of discharge
Method of measurement
Blood test (CBC/Diff)

Intervention groups

1

Description
Intervention group: Intervention group: Noncritical hospitalized COVID- 19 infected patients. After explaining the study and obtaining consent form the intervention group will be given 100 cc of hyperimmune milk as an evening meal.
Category
Treatment - Drugs

2

Description
Control group: Noncritical hospitalized COVID- 19 infected patients. After explaining the study and obtaining consent the control group will be given 100 cc of ordinary milk as an evening meal.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Somayeh Sadeghi
Street address

Soffe Blvd, Al-Zahra University Hospital

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
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Email
s.sadeghi117917@gmail.com

Web page address
http://alzahra.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

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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
Isfahan Science and Technology town

Full name of responsible person
Jafar Gheisary

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Isfahan University of Technology Blvd

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Email
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Web page address
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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
Isfahan Science and Technology town

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

3

Sponsor

Name of organization / entity
Zeitoon Isfahan Vaccine Innovators Company

Full name of responsible person
Hassan Nili Ahmadabadi

Street address
Parvin Street

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Postal code
8198887141

Phone
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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

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Somayeh Sadeghi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
pulmonologist
Street address
No. 4 apartment unit, Parmisa building, alley No. 5, Mehrabad avenue, Mehrabad neighbourhood
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Email
S.sadeghi117917@gmail.com

Person responsible for scientific 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
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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
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
City
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Postal code
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Email
nili@shirazu.ac.ir

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
Yes - There is 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
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

Results of the processed data would be available

When the data will become available and for how long

One year after termination of the project.

To whom data/document is available

Researchers and related authorities in health system on the bases of official request.

Under which criteria data/document could be used

In order to obtain required permission for production of the product.

From where data/document is obtainable

Written letter to researcher should be send and then after evaluation, proper decision will be made

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

Name and family name: Hassan Nili Ahmadabadi Email: hassanili@yahoo.com

Comments