

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Nilahmadabadi

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 $93\% \leq O_2 \text{ Sat}$ 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

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Isfahan

Province

Isfahan

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

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Postal code

8174675731

Phone

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+98 31 1668 4510

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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Isfahan

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Isfahan

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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

Street address

Isfahan University of Technology Blvd

City

Isfahan

Province

Isfahan

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Email

dabirkhane@istt.ir

Web page address

<https://www.istt.ir/>

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

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Parvin Street

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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 Niliahmadaadi

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
nili@shirazu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Virus research center of isfahan university

Full name of responsible person
Hassan Niliahmadaadi

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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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