

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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 40 patients. A random number table is used for randomization

##### Settings and conduct

In first phase of clinical trial hyperimmune bovine milk is given to 40 healthy men. If after 14 days 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 40 hospitalized patients of Alzahra-hospital once a day for 5 days 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 O<sub>2</sub>sat more than 92%; O<sub>2</sub> Sat more than 93%; Age more than 18; 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%≤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**

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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3620 2020

**Fax**

+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 Rognizadeh

**Street address**

Hezar Jerib Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3793 2171

**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**

Isfahan Science and Technology town

**Full name of responsible person**

Jafar Gheisary

**Street address**

Isfahan University of Technology Blvd

**City**

Isfahan

**Province**

Isfahan

**Postal code**

819887141

**Phone**

+98 31 3386 5355

**Fax**

+98 31 3386 2355

**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

**Street address**

Parvin Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

819887141

**Phone**

+98 31 3559 1831

**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

Subspecialist

**Other areas of specialty/work**

Virology

**Street address**

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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8198887141

**Phone**

+98 31 3261 6334

**Fax**

+98 31 3559 1833

**Email**

nili@shirazu.ac.ir

**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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8158913489

**Phone**

+98 31 3261 6331

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+98 31 3559 1833

**Email**

S.sadeghi117917@gmail.com

**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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8198887141

**Phone**

+98 31 3261 6334

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+98 31 3559 1833

**Email**

nili@shirazu.ac.ir

**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****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**