

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Study of the safety of hyperimmune bovine milk and colostrum against covid-19

Protocol summary

Study aim

Study of the safety of hyperimmune bovine milk and colostrum against Covid-19

Design

Clinical trial phase one, design of 40 healthy volunteers, non-random, without control group, with one intervention group, non-blinded.

Settings and conduct

After production of hyperimmune bovine colostrum and milk and receiving code of ethics from ethics committee of Isfahan University of Medical Sciences in the first phase of clinical trial (that the current clinical trial form is related to that) it is given to 40 healthy volunteer men that are interested in cooperation and participation in the study and consent form is filled by volunteers. If after 14 days they hadn't shown upper infection rate compared with ordinary people the trial goes to next phase.

Because the first phase is about assessing the immunity of the product the study is not blinded. Volunteer people live in Isfahan city and after receiving the milk will drink it in the presence of the executor. After 14 days the safety of the product is assessed through phone interview with volunteers. In the second phase hyperimmune colostrum and milk is given to 40 hospitalized patients of Alzahra hospital once a day for 5 days and their vital signs and experimental factors are assessed. Volunteer people should be interested in cooperation and participation in the study and sign the consent form.

Participants/Inclusion and exclusion criteria

-Inclusion Criteria Signing consent form of the study Free of underlying disease Not having clinical signs of Covid-19 infection -Exclusion Criteria Diseased person infected by Covid-19 or other diseases having underlying disease

Intervention groups

Intervention group is healthy volunteer people that will be given 100 cc of Hyperimmune milk and colostrum in the first day and after 14 days their clinical status will be

assessed through phone interview.

Main outcome variables

No complication and clinical symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200927048849N1**

Registration date: **2020-12-05, 1399/09/15**

Registration timing: **retrospective**

Last update: **2020-12-05, 1399/09/15**

Update count: **0**

Registration date

2020-12-05, 1399/09/15

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

2020-11-10, 1399/08/20

Expected recruitment end date

2020-11-25, 1399/09/05

Actual recruitment start date

2020-11-10, 1399/08/20

Actual recruitment end date

2020-11-25, 1399/09/05

Trial completion date

2020-11-25, 1399/09/05

Scientific title

Study of the safety of hyperimmune bovine milk and colostrum against covid-19

Public title

Study of the safety of hyper immune bovine milk and colostrum against covid-19

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Signing of consent form of the study Free of underlying disease Not having clinical signs of covid-19 infection

Exclusion criteria:

Diseased person Not having underlying disease

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Actual sample size reached: 40

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

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 viral pneumonia

ICD-10 code

J12.81

ICD-10 code description

Pneumonia due to SARS-associated coronavirus

Primary outcomes**1****Description**

Incidence of clinical symptoms

Timepoint

From the first day of using until 14 days after that

Method of measurement

Questionnaire through phone interview

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Healthy volunteers. After explaining the study and obtaining consent the intervention group will be given 100 cc of hyperimmune milk.

Category

Other

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 Roknizadeh

Street address

Hezar Jerib Street

City

Isfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۱

Phone

+98 31 3793 2171

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+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

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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

Street address

Parvin Street

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8198887141

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

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,
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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 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
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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 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
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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