Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ۱۴ 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-۱۹ 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
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 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
Isfehan
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
Isfehan
Postal code
۸۱۷۴۶۷۳۴۴۱
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
Isfehan
Postal code
۸۴۱۵۶۸۳۱۱۱
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
Isfehan
Postal code
8198887141
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

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
Isfehan

Postal code
8158913489

Phone
+98 31 3261 6331

Fax
+98 31 3559 1833

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

City
Isfahan

Province
Isfehan

Postal code
8198887141

Phone
+98 31 3261 6334

Fax
+98 31 3559 1833

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 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
Isfahan

Province
Isfehan

Postal code
8198887141

Phone
+98 31 3261 6334

Fax
+98 31 3559 1833

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