Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

"The effect of enteral bovine colostrum supplement on outcomes of critically ill patients with acute respiratory failure

Protocol summary

Study aim
Determining the effect of bovine colostrum supplementation on outcomes of critically ill patients with acute respiratory failure

Design
Single center, double-blind, randomized controlled clinical trial, grouped stratified blocked randomization method (4 blocks) using Random Allocation software.

Settings and conduct
This study is performed in the Intensive Care Unit (ICU) of Shohadaye Tajrish Hospital on patients with respiratory failure who are fed enteral nutrition. Patients in the intervention group receive 20 grams of bovine colostrum supplement daily and in the control group receive 20 grams of enteral high protein formula, which is similar in texture and appearance to colostrum. Colostrum and enteral formula are weighed by a non-researcher using a digital scale and poured into small bags and coded as A and B so that the researcher and patient does not know the type of formula received by patients in each group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: the patients with respiratory failure admitted to Intensive Care Unit; completion of informed consent form by the patient or legal guardian; feeding by enteral nutrition; exclusion criteria: no metastatic cancer or end stage disease; lack of intolerance to milk

Intervention groups
Patients in the intervention group received 20 gram of bovine colostrum powder daily with enteral formula and patients in the control group were fed only with enteral formula.

Main outcome variables
Incidence of nosocomial infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220425054648N1**
Registration date: **2022-06-24, 1401/04/03**
Registration timing: **prospective**

Last update: **2022-06-24, 1401/04/03**
Update count: **0**

Registration date
2022-06-24, 1401/04/03

Registrant information

Name
Elham Roohelhami

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4406 0328

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-01, 1401/04/10

Expected recruitment end date
2022-11-21, 1401/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
"The effect of enteral bovine colostrum supplement on outcomes of critically ill patients with acute respiratory failure

Public title
Bovine colostrum and acute respiratory failure
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with acute respiratory failure Completion of informed consent form by the patient or legal guardian Feeding by enteral nutrition 18-65 years old Body Mass Index less than 35 kg/m2
Exclusion criteria:
No metastatic cancer or end stage disease Lack of intolerance to milk (lactose) Don't participate in other clinical trial studies at the same time as the present study
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomly assign eligible individuals to two groups, the stratified blocked randomization method is used. The size of the blocks is 4, with two allocations to the intervention group (A) and two allocations to the placebo group (B), which creates 6 different permutations BAAB, BABA, ABBA, BBAA, ABAB, AABB. Randomization is performed using computer software.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients in the intervention group receive 20 grams of bovine colostrum powder daily with enteral high protein formula and patients in the control group are fed only with enteral high protein formula.Colostrum and a similar amount of isocaloric enteral formula are weighed by a non-researcher using a digital scale. Colostrum and formula are similar in texture and appearance. It is then poured into small bags and coded as A and B so that the researcher and patient are not aware of the type of formula received in each group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
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Tehran
Province
Tehran
Postal code
1981619573
Approval date
2022-03-14, 1400/12/23
Ethics committee reference number
IR.SBMU.NNFTRI.REC.1401.006

Health conditions studied

1

Description of health condition studied
Respiratory Failure
ICD-10 code
J96.9
ICD-10 code description
Respiratory failure, unspecified

Primary outcomes

1

Description
Incidence of nosocomial infection
Timepoint
The incidence of nosocomial infection is assessed up to 3 days after discharge from the hospital.
Method of measurement
The incidence of nosocomial infection is based on the results of laboratory tests and medical records.

Secondary outcomes

1

Description
The Mean concentration of serum CD markers (CD4, CD8)
Timepoint
The CD markers (CD4, CD8) variable are measured at the beginning and end of the intervention.
Method of measurement
Evaluation of CD marker variables (CD4, CD8) are

performed using ELISA method and related kits.

2

Description
The Mean concentration of serum Insulin-like Growth Factor1
Timepoint
The Insulin-like Growth Factor1 variable is measured at the beginning and end of the intervention.
Method of measurement
Evaluation of Insulin-like Growth Factor1 is performed using ELISA method and related kits.

3

Description
Duration of hospitalization in the hospital, duration of hospitalization in the intensive care unit
Timepoint
The evaluation of these variables is from the beginning of the intervention to the time of hospitalization of the patient in the hospital and intensive care unit.
Method of measurement
The evaluation of these variables is based on the information recorded in the patients' hospital records.

4

Description
Patient mortality rate in hospital and intensive care unit
Timepoint
The evaluation of these variables is from the beginning of the intervention to the time of possible death of the patient in the hospital and intensive care unit.
Method of measurement
The evaluation of these variables is based on the information recorded in the patients' hospital records.

5

Description
Gastrointestinal complications (diarrhea, constipation, nausea, abdominal distension)
Timepoint
Evaluation of these variables is from the beginning of the intervention to the end of the intervention.
Method of measurement
Based on reports recorded in the patient's file

Intervention groups

1

Description
Control group: Patients in this group receive 20 grams of enteral high protein formula (Karen Pharma & Food Supplement, Co., Tehran, Iran) once a day for a minimum of 5 days and a maximum of 10 days as a placebo, which is similar in appearance, color and texture to bovine colostrum powder.
Category
Other

2

Description
Intervention group: Patients in this group receive 20 grams of bovine colostrum supplement (Global Nature, New Zealand) daily for a minimum of 5 days and a maximum of 10 days. This supplement is similar to the received enteral protein formula in terms of appearance, color and texture.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Tajrish Hospital
Full name of responsible person
Hossein Ardehali
Street address
Shohadaye Tajrish Hospital., Shahrdari Ave., Qods Sq., Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National Nutrition & Food Technology Research Institute
Full name of responsible person
Azita Hekmatdoost
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
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1981619573
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nutrition@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
National Nutrition & Food Technology Research Institute

Proportion provided by this source
100

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

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Elham Rouhelhami

Position
PhD candidate

Latest degree
Master

Other areas of specialty/work
Nutrition

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Associate professor

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Position
PhD candidate

Latest degree
Master

Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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