Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of probiotics in reducing gavage return in intensive care unit patients: a randomized clinical trial

Protocol summary

Study aim

The objective of the study is to investigate the effectiveness of probiotics in reducing the incidence and severity of gastroesophageal reflux, vomiting, and diarrhea in adult Intensive Care Unit (ICU) patients who require enteral nutrition.

Design

This study is a randomized, double-blind clinical trial in which participants are randomly assigned to two groups: Group 1: Participants in this group will receive one capsule containing Lactobacillus casei daily. Group 2: Participants in this group will receive one capsule containing a placebo daily. The study will last for 14 days. At the end of the study, researchers will assess the incidence and severity of adverse events in both groups.

Settings and conduct

This study is a randomized, double-blind, placebo-controlled clinical trial that will be conducted at the Labbafinejad Hospital in Tehran, Iran. Participants in the study will be hospitalized patients in the intensive care unit (ICU) who are receiving enteral nutrition, which is a type of nutrition that is delivered through a tube inserted into the stomach or intestines.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1-En Adult patients (18 years of age or older) admitted to the intensive care unit (ICU) 2-Patients requiring tube feeding 3-Patients with symptoms of gastroesophageal reflux (GERD), such as vomiting, diarrhea, nausea, etc. Exclusion criteria: 1-En Presence of underlying GI disease 2-Prior antibiotic use 3-Known allergy to probiotic ingredients 4-Pregnancy or lactation 5-Coagulation disorders or thrombocytopenia

Intervention groups

Probiotic group receiving Lactobacillus casei capsules" This group was randomly selected and will receive probiotic capsules containing Lactobacillus casei for 14 days.

Main outcome variables

Incidence and severity of regurgitation, vomiting, and diarrhea"

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190215042716N4**
Registration date: **2023-12-09, 1402/09/18**
Registration timing: **prospective**

Last update: **2023-12-09, 1402/09/18**
Update count: **0**

Registration date

2023-12-09, 1402/09/18

Registrant information

Name
navid shafigh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8801 3378

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n.shafigh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-12-21, 1403/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotics in reducing gavage return in intensive care unit patients: a randomized clinical trial

Public title

Probiotics: A Promising Strategy to Reduce gavage return

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients (18 years of age or older) admitted to the intensive care unit (ICU) Patients requiring tube feeding Patients with symptoms of gastroesophageal reflux (GERD), such as vomiting, diarrhea, nausea, etc.

Exclusion criteria:

Presence of underlying GI disease Prior antibiotic use Known allergy to probiotic ingredients Pregnancy or lactation Coagulation disorders or thrombocytopenia

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization was performed using computerized randomization. In this method, a computer uses a random algorithm to assign participants to the intervention and control groups. In this study, randomization was performed as follows: 1-The name and case number of all potential patients were entered into a computerized database. 2-A random algorithm was used to assign patients to the intervention and control groups. 3-The results of randomization were kept confidential from the study team. We will use statistical software such as SAS or SPSS to generate random allocation sequence. Specifically, a randomization feature of the software will be utilized. We will create two equal groups of 30 participants by specifying group size parameters. The software has a random allocation algorithm which will assign each participant ID to either group 1 (intervention) or group 2 (control) entirely at random. This results in two groups that have participants assigned in a random order determined computationally by the software. At this stage, the two groups are randomized and researchers/participants are still blinded to the allocation (double blinding). Then the randomized group assignments will be implemented accordingly - group 1 receives probiotic capsules and group 2 receives placebo capsules for the 14 day intervention period. Final data analysis will combine all results from both groups, still in a blinded fashion. Only after statistical analysis is complete, the randomization code will be broken to determine which group was probiotic intervention vs placebo control to interpret the actual effect of the probiotic supplement.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, blinding was performed using double-blinding. In this method, participants, researchers, and other study personnel are unaware of the intervention and control groups. In this study, blinding was performed as follows: Participants were randomly assigned to intervention and control groups. Researchers and other study personnel were not informed of the results of randomization. Participants and researchers were informed of their intervention and control group through a coded system. This ensured that participants, researchers, and other study personnel were unaware of the intervention and control groups.

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 and Health Services

Street address

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-09-05, 1402/06/14

Ethics committee reference number

IR.SBMU.MSP.REC.1402.444

Health conditions studied

1

Description of health condition studied

Gastric regurgitation

ICD-10 code

K21

ICD-10 code description

Gastro-esophageal reflux disease

Primary outcomes

1

Description
Incidence and severity of regurgitation, vomiting, and diarrhea"
Timepoint
Daily
Method of measurement
measured using 24-hour nursing charting forms.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Probiotic group receiving Lactobacillus casei capsules "This group was randomly selected and will receive probiotic capsules containing Lactobacillus casei for 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Labbafinezhad Hospital
Full name of responsible person
Navid shafigh
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9th Boostan, Pasdaran St.
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
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
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Navid Shafigh
Position
Assistant Professor
Latest degree
Subspecialist
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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The whole potential data after being unidentifiable is published
When the data will become available and for how long
One year
To whom data/document is available
Medical Society
Under which criteria data/document could be used
Contributing to studies
From where data/document is obtainable
Email: n.shafigh@sbmu.ac.ir
What processes are involved for a request to access data/document
Tho months
Comments