Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation the effect of oral probiotics on enteral nutrition tolerance in patients admitted to intensive care units: a double-blind randomized controlled trial

Protocol summary

Study aim

Investigating the effect of probiotic consumption on improving oral nutrition tolerance in hospitalized patients in the intensive care unit.

Design

This study is a prospective, double-blind, randomized controlled clinical trial (phase 2), 100 patients will randomly, Using Random allocation software (version 1.0), assign to the control or intervention group (50 in each group). The Nutritionist, student in charge of completing the questionnaires and the patient will not be notified of any grouping. In the intervention group, patients will receive Familact probiotic capsules twice daily in addition to routine care and will be followed up for 7 days. In the control group, patients will receive a placebo capsule in addition to routine care.

Settings and conduct

The gavage composition received in all patients during the study period will be the standard Intramil formula. Gastronazal tube type will be the same in all patients and number 16. The NG tube will be connected to a 60 cc syringe. All stages will be hidden from the patient, the treating physician, and the evaluators. Only the person in charge of preparing the gavage will know the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Age over 18 years 2) No history of GI injury during hospitalization 3) Nutrition through the nasal tube (gavage) Exclusion criteria: 1) bleeding disorders or having an INR above 2 2) drug or alcohol abuse 3) Failure to sign a written consent 4) Pregnancy and lactation

Intervention groups

A group receiving probiotic capsules is a femme lactate and a group receiving normal care.

Main outcome variables

Delayed gastric emptying, recurrence of gastric contents into the esophagus, Frequent need for prokinetics, diarrhea (three or more loose stools in the last 24 hours), or constipation (No stool for the past three days).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190810044500N13**
Registration date: **2021-05-20, 1400/02/30**
Registration timing: **retrospective**

Last update: **2021-05-20, 1400/02/30**
Update count: **0**

Registration date

2021-05-20, 1400/02/30

Registrant information

Name

Fatemeh Saghafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3419

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the effect of oral probiotics on enteral nutrition tolerance in patients admitted to intensive care units: a double-blind randomized controlled trial

Public title
Effect of oral probiotics on enteral nutrition
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
No history of GI injury during hospitalization intestinal feeding through the nasal tube (gavage) over 18 years of age
Exclusion criteria:
Hemorrhagic disorders or having an INR above 2 substance or alcohol abuse failure to sign written consent for pregnancy and lactation
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

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

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
First, using Random allocation software (version 1.0), we generate a random sequence by a simple random allocation method. In this table, we specify from 1 to 64 and each number is assigned to an intervention group (A or B). The first eligible person is referred to as number 1, the second person as number 2, and so on up to 64 patients. To be blind to random allocation, patients are placed in one of the intervention groups (A or B) according to the table by a third person who is unaware of the interventions
Blinding (investigator's opinion)
Double blinded
Blinding description
All stages are hidden from the patient, the treating physician and the evaluators. Only the hospital's nutritionist, who is responsible for overseeing the preparation of patients' gavage, will be aware of the type of intervention. Nursing staff, physicians, and anesthesiologists will not be aware of the type of intervention. Due to the fact that both Formula Intramil powder and probiotic powder are white, it will not be possible to distinguish the type of intervention from the appearance of the product. To do this, mixing Intramill powder with probiotics or mixing Intramill powder with placebo is done in the hospital kitchen and by a nutritionist.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Sadoughi University of Medical Sciences
Street address
Gomnam shohada boulevard - Shahid Sadoughi University of Medical Sciences
City
Yazd
Province
Yazd
Postal code
8915173143
Approval date
2019-12-04, 1398/09/13
Ethics committee reference number
IR.SSU.MEDICINE.REC.1398.244

Health conditions studied

1

Description of health condition studied
Endurance nutrition tolerance in hospitalized patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Delay in gastric emptying
Timepoint
Every day for 7 days
Method of measurement
The remaining volume of the stomach

2

Description
Return the contents of the stomach to the esophagus
Timepoint

Every day for 7 days

Method of measurement

The remaining volume of the stomach

3

Description

Diarrhea

Timepoint

Every day for 7 days

Method of measurement

Number of loose stools per day

4

Description

Constipation

Timepoint

Every day for 7 days

Method of measurement

No stool in the last three days

Secondary outcomes

1

Description

Mortality rate

Timepoint

Everyday

Method of measurement

Examining vital signs

2

Description

Duration of stay in the intensive care unit and hospital

Timepoint

Everyday

Method of measurement

Number of days in the hospital

Intervention groups

1

Description

Intervention group: In this group, we give Familact probiotic powder in the amount of one gram and twice a day for seven days with Intramil powder to patients.

Category

Treatment - Drugs

2

Description

Control group: In this group, we give placebo powder in the amount of one gram and twice a day for seven days with Intramil powder to patients.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahnemon Hospital

Full name of responsible person

Zeynab Bordbari

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Twentieth alley.,Pasdaran Blvd.,Yazd

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Web page address

https://web.ssu.ac.ir/index.aspx?lang=1&sub=4

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mohamad Reza Mirjalili

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

100

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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Fatemeh Saghafi
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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