

# 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

f.saghafi@ssu.ac.ir

##### 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 Intramil powder with probiotics or mixing Intramil 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

**Street address**

Twentieth alley.,Pasdaran Blvd.,Yazd

**City**

Yazd

**Province**

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**Phone**

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**Email**

zeynab8754@gmail.com

**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

**Street address**

Bahonar Square

**City**

Yazd

**Province**

Yazd

**Postal code**

8916978477

**Phone**

+98 35 3724 1171

**Fax**

**Email**

ravabet@SSU.AC.IR

**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

+98 35 3820 3419

## Email

Saghfi.Fa@gmail.comhs

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Yazd University of Medical Sciences

#### Full name of responsible person

Fatemeh Saghafi

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

#### Street address

Professor Hesabi Blvd., Yazd Province, Yazd, Iran

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#### Province

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#### Postal code

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## Person responsible for updating data

### Contact

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Yazd University of Medical Sciences

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

Fateme saghafi

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#### Phone

## 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