

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jul 2026

### Evaluation of the effects of probiotics on the prevalence of ventilator-associated pneumonia in patients with multiple trauma admitted to the intensive care unit of brain surgery

#### Protocol summary

##### Study aim

Evaluation of the effects of probiotics on the prevalence of ventilator-associated pneumonia in patients with multiple trauma admitted to the intensive care unit of brain surgery

##### Design

This randomized clinical trial (quadruple blocks) was performed with the control group, not blinded and in parallel groups with the participation of 150 patients admitted to the intensive care unit.

##### Settings and conduct

This randomized trial study was performed with the participation of 150 patients admitted to the intensive care unit of Imam Reza Hospital in Tabriz. No blinding was performed in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included: required mechanical ventilation and exclusion criteria included death during the intervention and history of lung disease.

##### Intervention groups

Participants were divided into two groups. The intervention group received one probiotic capsule every twelve hours by gavage and the control group received one placebo capsule every twelve hours by gavage.

##### Main outcome variables

Ventilator-associated pneumonia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190325043107N18**

Registration date: **2020-10-30, 1399/08/09**

Registration timing: **prospective**

Last update: **2020-10-30, 1399/08/09**

Update count: **0**

##### Registration date

2020-10-30, 1399/08/09

##### Registrant information

###### Name

Mehdi Khanbabayi Gol

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3334 7054

###### Email address

khanbabayimehdi69@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2020-11-20, 1399/08/30

##### Expected recruitment end date

2021-01-19, 1399/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effects of probiotics on the prevalence of ventilator-associated pneumonia in patients with multiple trauma admitted to the intensive care unit of brain surgery

##### Public title

Effects of probiotics on the prevalence of ventilator-associated pneumonia

##### Purpose

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Requires mechanical ventilation

**Exclusion criteria:**  
Death during intervention History of lung disease

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **150**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
By randomization method, 4 permutation blocks were assigned to one of the two intervention and placebo groups; Thus, first 6 possible modes of 4 blocks (BAAB, ABBA, BABA, AAB, ABAB, BBAA) were listed and a number from 1 to 0 was assigned to each block. Then, a number between 1 and 0 was randomly selected and the subjects were assigned to the intervention group (A) and placebo (B) based on the relevant block and the selected number. This was continued until the sample size was completed.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Imam Reza Hospital, Azadi Ave

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5165665631

#### Approval date

2018-09-10, 1397/06/19

#### Ethics committee reference number

IR.TBZMED.REC.1397.499

## Health conditions studied

### 1

#### Description of health condition studied

Ventilator-associated pneumonia

#### ICD-10 code

J95.851

#### ICD-10 code description

Ventilator associated pneumonia

## Primary outcomes

### 1

#### Description

Ventilator-associated pneumonia

#### Timepoint

Every 12 hours for three days

#### Method of measurement

Physical examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: At the beginning of the study, the patients received two daily Lactocare capsules (Bio-Fermentation Pharmaceutical Company-Tehran-Iran) with 20cc of distilled water through NG tube once every twelve hours (9 o'clock in the morning and evening - at least two hours after the last NG tube)

#### Category

Prevention

### 2

#### Description

Control group: In the control group, a starch capsule was used as a placebo, which was given to the patient by gavage (twice daily - once every twelve forearms - at 9 am - at least two hours after the last gavage).

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital

##### Full name of responsible person

Mehdi Khanbabayi Gol

##### Street address

Azadi Ave, Shahid Madani Hospital

##### City

Tabriz  
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East Azarbaijan  
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5981764863  
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**Email**  
mkhanbabayi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Abolghasem Jouyban  
**Street address**  
Imam Reza Hospital, Azadi Ave  
**City**  
Tabriz  
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East Azarbaijan  
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5165665631  
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+98 41 3335 7310  
**Email**  
Ajouyban@hotmail.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Tabriz University of Medical Sciences  
**Proportion provided by this source**  
30  
**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**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Mehdi Khanbabayi Gol  
**Position**  
MSc in Nursing Education  
**Latest degree**  
Master  
**Other areas of specialty/work**

Nursery  
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## Person responsible for scientific inquiries

#### Contact

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**Other areas of specialty/work**  
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## Person responsible for updating data

#### Contact

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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