

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)

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+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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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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
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
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Other areas of specialty/work

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Person responsible for updating data

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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