Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

Effect of probiotic prophylaxis on the prevention of ventilator-associated pneumonia (VAP) in patients admitted to the intensive care unit (ICU)

Protocol summary

Study aim

Effect of probiotic prophylaxis on the prevention of ventilator associated pneumonia (VAP) in ICU patients

Design

A clinical trial with a control group with parallel and two-way blind groups, randomized by systematic random sampling method in such a way that an alphabetically sorted list of patients admitted to the intensive care unit . The determination of intervention and control groups will be based on the last digit of the patient's admission code ; Phase 3 on 134 patients .

Settings and conduct

Patients under mechanical ventilation and hospitalized in the General ICU of Masih Daneshvari Hospital. The examining doctor, the nurse prescribing medicine and placebo, the doctor recording vital signs do not know about the control and intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include all patients over 18 years of age and intubated under mechanical ventilation in the intensive care unit. Exclusion criteria include the patient's diagnosis of VAP upon arrival; pregnancy ; prosthetic heart valve ; prosthetic vascular graft; immunosuppression ; history of rheumatic fever ; history of gastrointestinal damage in the current admission ; tracheostomy; unwillingness of the patient or his parents ; Intolerance of gavage .

Intervention groups

The intervention group will be prescribed probiotic capsule by gavage and will also receive other standard treatments. The control group will receive standard treatments along with placebo capsules . Standard treatments to prevent VAP include position of the upper body at an angle of 30 degrees ; oral hygiene with chlorhexidine mouthwash ; interruption of sedation during daily periods and waking up the patient ; daily periods of spontaneous breathing .

Main outcome variables

Ventilator associated pneumonia; Length of stay in ICU; Length of antibiotic therapy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230611058449N1**
Registration date: **2023-06-27, 1402/04/06**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-27, 1402/04/06**
Update count: **0**

Registration date

2023-06-27, 1402/04/06

Registrant information

Name

Ali Nazembokaee

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-19, 1402/03/29

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of probiotic prophylaxis on the prevention of ventilator-associated pneumonia (VAP) in patients admitted to the intensive care unit (ICU)

Public title
Effect of probiotic prophylaxis on ventilator-associated pneumonia

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
All patients over the age of 18 that are intubated in the intensive care unit

Exclusion criteria:
Diagnosis was ventilator-associated pneumonia from beginning Diagnosis was pneumonia from beginning Pregnancy Prosthetic heart valves Prosthetic vascular grafts Immunosuppress History of rheumatic fever History of gastrointestinal tract injury in the current hospitalization Having tracheostomy Lack of consent of the patient or her or his parents Gavage intolerance

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **134**

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling method in this study will be systematic random sampling .For each patient in the first group, we will have one patient in the second group. The determination of the people of the first and second groups will be based on the last digit of the patient's admission code. In this way, the first patient whose last digit of their code is odd is placed in the intervention group, and vice versa, the first patient whose last digit of their code is even is placed in the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient does not know which group is the study or the control group, the control group will receive standard treatments along with placebo capsules that look similar to the original capsules produced by Tekgen Biot. The number of drugs, the nurse who prescribes the drug, the examining doctor and the doctor who registers the vital signs do not know about the patient group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee in medical school research

Street address
Sixth floor ; 2nd Building ; Shahid Beheshti University of Medical Sciences ; Arabi street ; Yemen Street ; Shahid Chamran Highway ; Tehran

City
Tehran

Province
Tehran

Postal code
1983969411

Approval date
2023-05-27, 1402/03/06

Ethics committee reference number
IR.SBMU.MSP.REC.1402.096

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
Clinical Pulmonary Infection Score

Timepoint
Clinical Pulmonary Infection Score at the beginning of the study and the third day after probiotic consumption.

Method of measurement
Clinical Pulmonary Infection Score using ; body temperature ; leukocyte count and morphology , tracheal secretion volume and character , PaO2/FiO2 values , presence of pulmonary infiltration ; Tracheal aspirate culture

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients over 18 years of age and intubated with mechanical ventilation randomly placed in the intervention group of this study will use BioIBS probiotic capsules produced by Tekgen Biot Company, each capsule containing 5 x 10 to the power of 9 Lactobacillus Casei, Lactobacillus Rhamnosus, Lactobacillus Acidophilus . The prescribed dosage of probiotics will be one capsule every 12 hours for 15 days. They will also receive other standard treatments to prevent ventilator-associated pneumonia , which include position of the head and upper body at an angle of 30 degrees; Oral hygiene of the patient with chlorhexidine mouthwash; Cessation of sedation during daily periods and waking the patient up; Daily periods of spontaneous breathing of the patient.

Category

Treatment - Drugs

2

Description

Control group: Patients over 18 years of age and intubated and connected to mechanical ventilation were randomly placed in the control group of this study and will receive standard treatments along with placebo capsules that look similar to the original capsules produced by Tekgen Biot. Standard treatments to prevent They will also receive ventilator-related lung infection, which include: position of the head and upper body at an angle of 30 degrees, oral hygiene of the patient with chlorhexidine mouthwash, interruption of sedation during daily periods and waking up the patient, daily periods of spontaneous breathing of the patient.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Ali Nazembokaee
Street address
Darabad ; Shahid Bahonar St. (Niavaran)
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Darabad ; Shahid Bahonar Street (Niavaran)
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Email
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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
Full name of responsible person
Ali Nazembokaee
Position
Fellow Assistant of Critical Care Medicine
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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