

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 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 Nazembokae

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2267 1195

Email address

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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 BiolBS 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 Nazembokae

Street address

Darabad ; Shahid Bahonar St. (Niavaran)

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1956944413

Phone

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Email

ali_nb@Yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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 Nazembokae

Position

Fellow Assistant of Critical Care Medicine

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Position

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Latest degree

Specialist

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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