

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Investigation of probiotic effects on prophylaxis of ventilator - associated pneumonia in ICU patients

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Determining the role of probiotics in reduction of ICU patients' infections

Design

Two arm parallel group randomized trial on ICU patients, not blinded , simple randomization according to the Random numbers table

Settings and conduct

The study is conducted on 100 patients admitted to ICU who are not suffering from pneumonia or pulmonary involvement. The patients are randomly divided into two groups of 50. One group - in addition to prescription drugs and antibiotics- are given probiotics as prophylaxis of ventilator associated pneumonia(VAP), and the other only receives medications prescribed by a specialist. Ventilator associated pneumonia will be examined in two groups .

Participants/Inclusion and exclusion criteria

Age over 18 years , length of stay in ICU for more than 5 days, absence of diarrhea within 48 hours before admission, lack of immune deficiency history, lack of regular treatment with probiotics before admission, non pregnant

Intervention groups

One group - in addition to prescription drugs and antibiotics - are given probiotics as prophylaxis of pneumonia associated with ventilation (VAP), and the other only receives medications prescribed by the specialist.

Main outcome variables

ventilator associated pneumonia , age , probiotic

Last update: **2018-05-29, 1397/03/08**

Update count: **0**

Registration date

2018-05-29, 1397/03/08

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3244 4453

Email address

rezaeemaliheh@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of probiotic effects on prophylaxis of ventilator - associated pneumonia in ICU patients

Public title

investigation of probiotic effects on prophylaxis of pneumonia

Purpose

Prevention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170704034901N2**

Registration date: **2018-05-29, 1397/03/08**

Inclusion/Exclusion criteria

Inclusion criteria:

age over than 18 year Length of stay in ICU for more than 5 days

Exclusion criteria:

Diarrhea at first visit or 48 hours before admission
immune deficiency Regular treatment with probiotics before admission pregnancy

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method , using the Random numbers table , individual randomization

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Ghaffari ave

City

Birjand

Province

South Khorasan

Postal code

941453577

Approval date

2018-02-06, 1396/11/17

Ethics committee reference number

lr.bums.REC.1396.337

Health conditions studied

1

Description of health condition studied

Ventilator associated pneumonia(VAP)

ICD-10 code

J15

ICD-10 code description

Bacterial pneumonia, not elsewhere classified

Primary outcomes

1

Description

The incidence of ventilator associated pneumonia(VAP)

Timepoint

Up to 15 days after starting probiotics, ventilator-associated pneumonia will be examined.

Method of measurement

Daily hematologic examination (CBC and neutrophil count), active phase proteins (CRP or prolotonin or ferritin) and chest X ray, Based on the American College of Chest Physicians clinical criteria, new or sustained infiltration in the CXR with 2 or 3 of the following findings: fever (.38.58C or ,35.08C), leukocytosis (white bloodcells . 10,000/mm3 or ,3,000/mm3), and purulent sputum.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients receive the first dose of probiotics during the first 24 hours of intubation and, until extubation or up to 10 days after the intubation, every 12 hours, one tablet of vitalact (each tablet contains 10⁹ CFU of lactobacillus gasseri, Bifidobacterium bifidum, Bifidobacterium longum and multivitamin And mineral. Of Iran's Bioscience Company).

Category

Prevention

2

Description

Control group: This group does not take any special medication.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital, Imam Reza Hospital

Full name of responsible person

Maliheh Rezaei

Street address

Imam Reza Hospital, Taleghani Ave., Razi Hospital,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand 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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Dr. Farshid Abedi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

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Full name of responsible person

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General Practitioner

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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