

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

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

#### Protocol summary

##### 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

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170704034901N2**

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

Registration timing: **registered\_while\_recruiting**

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

## 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

971783577

#### 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 proxlotonin 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 10<sup>9</sup> 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,  
Ghaffari St.

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3239 5000

**Fax**

+98 56 3243 0076

**Email**

rezaemaliheh@bums.ac.ir

**Web page address**

<http://www.bums.ac.ir/>

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Dr. Tooba Kazemi

**Street address**

Birjand University of Medical Sciences, Ghaffari ave

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3244 0388

**Fax**

+98 56 3244 0388

**Email**

drtooba.kazemi@gmail.com

**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

**Street address**

Birjand University of Medical Sciences, Ghaffari ave

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3238 5600

**Fax**

+98 56 3244 0447

**Email**

abedifar@yahoo.com

## Person responsible for scientific 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

**Street address**

Birjand University of Medical Sciences, Ghaffari ave

**City**

Birjand

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**Postal code**

9717853577

**Phone**

+98 56 3238 5600

**Fax**

+98 56 3244 0447

**Email**

abedifar@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Maliheh Rezaei

**Position**

Intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

No. 84, Modares 30, Modares Street, Birjand

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9718685191

**Phone**

+98 56 3244 4453

**Email**

rezaeemaliheh@gmail.com

**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