

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of Probiotics on Ventilator Associated Pneumonia in Adult Patients in Intensive Care Unit

Protocol summary

Summary

Objectives: The aim of this study was to investigate the incidence of ventilator associated pneumonia (VAP) in 140, ICU patients with oral preventive probiotics in the treatment group and the placebo in the control group.

Research design: A randomized, double-blind, respective study. Inclusion criteria: age of eighteen years and above, the consent of relatives, patients with tracheal intubation and mechanical ventilation which will be continued to the next 72 hours, patients' intubation must not be for more than 48 hours, starting patients' feeding until 24 hours. Exclusion criteria: pregnancy, weakened immune system due to any reason, suppressor of the immune system, replacement heart valves, vascular grafts, heart trauma, history of rheumatic fever, endocarditis, congenital anomaly of heart, injury of stomach, esophagus, bowel, injury to airway, pancreatitis and base skull fracture . Sample Size: 140 patients found eligible based on the inclusion criteria. Interventions: intervention group received probiotics capsule once daily and in the control group, placebo once daily were used. While, Staphylococcus aureus, Pseudomonas and Klebsiella, Acinetobacter were the most common bacteria and the diagnosis of VAP will be based on the culture of sputum culture of BAL. Intervention time: immediately after admission of the qualified patients into the study.

General information

Acronym

VAP(Ventilator Associated Pneumonia)

IRCT registration information

IRCT registration number: **IRCT2014051417691N1**

Registration date: **2014-12-16, 1393/09/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-16, 1393/09/25

Registrant information

Name

Gholamreza Dabiri

Name of organization / entity

Shiraz University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Probiotics on Ventilator Associated Pneumonia in Adult Patients in Intensive Care Unit

Public title

Effect of Probiotics on Ventilator Associated Pneumonia in Intensive Care Unit

Purpose

Prevention

Inclusion/Exclusion criteria

Including criteria: Age above 18 ; Special concept from first relatives; Endotracheal tube for at least 72 hrs.
Exclusion criteria : Pregnancy; Immune-suppression; Prosthetic cardiac valve; Vascular graft ; Cardiac trauma; History of rheumatic fever; Endocarditis; Congenital cardiac abnormality; Gastroesophageal or intestinal injury; Pancreatitis ; Fracture base skull

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Shiraz University Of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

CT-P-9341-4681

Health conditions studied

1

Description of health condition studied

Pneumonia

ICD-10 code

J15

ICD-10 code description

Bacterial Pneumonia not Elsewhere Classified

Primary outcomes

1

Description

Ventilator Associated Pneumonia

Timepoint

During Hospitalization in ICU

Method of measurement

Microbial Culture

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group we used one capsule of probiotic blend: cfu 10^5 ,every day orally for each patient during the hospitalization in the ICU.

Category

Treatment - Drugs

2

Description

In control group one capsule of placebo is used everyday orally for each patient during the hospitalization in the ICU.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajae Hospital

Full name of responsible person

Gholamreza Dabiri

Street address

Rajae Hospital, Chamran Boulevard

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

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University of Medical Sciences, Zand Street

City

Shiraz

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Position

Anesthesiologist, Intensive Care fellowship

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty