

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Effect of probiotics on pathogenic bacteria in the stomach seminars adult patients undergoing mechanical ventilation in the intensive care unit, a clinical trial

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 6 days with probability of 95%, 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. **Sample Size:** 68 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

Effect of probiotics on pathogenic bacteria in the stomach seminars adult patients undergoing m

IRCT registration information

IRCT registration number: **IRCT2012101211091N1**

Registration date: **2015-01-28, 1393/11/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-28, 1393/11/08

Registrant information

Name

Majid Yazdani

Name of organization / entity

Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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yazdanim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Science

Expected recruitment start date

2013-09-01, 1392/06/10

Expected recruitment end date

2015-04-30, 1394/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotics on pathogenic bacteria in the stomach seminars adult patients undergoing mechanical ventilation in the intensive care unit, a clinical trial

Public title

Effect of probiotics on pathogenic bacteria in the stomach seminars adult patients undergoing mechanical ventilation in the intensive care unit, a clinical trial

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: at least 18 years; the consent of the relatives; unconscious patients with endotracheal tube and under mechanical ventilation; probability of 95% for continuing these circumstances within the next six days; patients within 24 hours of abolished the NPO. Exclusion criteria: pregnancy; weakened immune system due to any reason (HIV, leukemia; lupus; donors receive a suppressed immune systems; heart valve replacement; eclipses, vascular; cardiac trauma; history of rheumatic fever; endocarditis; congenital heart anomalies; injuries of stomach; esophagus or intestine; airway injuries; tracheostomy; pancreatitis.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 68

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
7149713717

Approval date
2013-02-21, 1391/12/03

Ethics committee reference number

ct- 92-6947

Health conditions studied

1

Description of health condition studied

Ventilator Associated Pneumonia

ICD-10 code

j15

ICD-10 code description

Bacterial Pneumonia not Elsewhere Classified

Primary outcomes

1

Description

To determine the bacteria in the throat

Timepoint

from arrival to the ICU untill 24 hours

Method of measurement

Colonies Count

Secondary outcomes

empty

Intervention groups

1

Description

Prescribe 1 capsule of probiotics (lactocare) which contains 6.18×10^{10} coloni of seven probiotics.

Category

Treatment - Drugs

2

Description

1 capsule of placebo

Category

Placebo

3

Description

Take a throat culture in the fourth and sixth day after the first culture

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajae Hospital

Full name of responsible person

Majid Yazdani

Street address

Anesthesiology Office, Namazi Hospital, Zand Street

City

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

Street address

Vice Chancellor for Research, Shiraz University of Medical Sciences, 7th floor, Central Building of Shiraz 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

Vice Chancellor for Research, 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**

Shiraz University of Medical Sciences

Full name of responsible person

Majid Yazdani

Position

Nurse

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

English Consultant, Anesthesiology Research Center Staff

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Web page address**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