

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The role of probiotics in the prevention of ventilator-associated pneumonia in patients admitted to intensive care units

Protocol summary

Summary

Given the role of probiotics in balancing the organisms in the digestive system, and considering the central role of bacterial colonization in the pathogenesis of ventilator-associated pneumonia (VAP), this study aims to investigate the effect of using probiotics as an adjuvant treatment for the prevention of VAP in mechanically ventilated patients. This double-blind randomized clinical trial is conducted on 60 mechanically ventilated patients who are at high risk of developing VAP, and who are selected among the patients admitted to the ICUs of the Vali-e-Asr Hospital in Arak, Iran. The participants of this study include all mechanically ventilated patients admitted to ICU who, according to clinical criteria and their doctors' opinion, should undergo intubation for at least 72 hours. Before patients enter the study, informed consents are obtained from their guardians. However, patients with major systemic diseases and pneumonia are excluded from the study on admission. Patients are then randomly divided into two groups with equal number of members; namely, the probiotic (intervention) and the control (placebo) groups. In addition to receiving routine preventive treatments for VAP, the intervention group also receives *Lactobacillus rhamnosus* GG probiotic via gavage 3 times a day. However, the control group is given the routine treatment and the placebo. Patients' clinical and demographic information is recorded, and clinical response is interpreted as primary outcome (frequency of VAP) and secondary outcome (complications of VAP and degree of improvement or death).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090114170N1**

Registration date: **2016-06-04, 1395/03/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-04, 1395/03/15

Registrant information

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Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of probiotics in the prevention of ventilator-associated pneumonia in patients admitted to intensive care units

Public title

Assessing the application of beneficial bacteria in the prevention of ventilator-induced lung infections in patients in intensive care unit

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with Endotracheal intubation and mechanical ventilation that according to the doctors idea the possibility of 95% for at least 72 hours will be intubation; Obtaining the informed consent of the guardian of the patients. Exclusion criteria: pregnant patients; immunosuppressive; prostatic heart valves; vascular grafts; heart trauma; history of rheumatic fever; endocarditis; congenital heart anomalies; gastro-intestinal damage; foregut surgery in this hospitalization; oropharyngeal mucosa damage; tracheostomy; patients unable to get probiotics in the first 24 hours after intubation; pneumonia at admission; history of antibiotics in the 4 weeks prior to admission to the ICU

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Research Ethics Committee, Arak University of Medical Sciences, Basij square, Arak, Iran

City

Arak

Postal code

3819164451

Approval date

2013-06-16, 1392/03/26

Ethics committee reference number

92-144-4

Health conditions studied

1

Description of health condition studied

pneumonia

ICD-10 code

J18.9

ICD-10 code description

Pneumonia, unspecified

Primary outcomes

1

Description

Developing of ventilator-associated pneumonia

Timepoint

The time of Developing of ventilator-associated pneumonia

Method of measurement

Diagnostic criteria of ventilator-associated pneumonia

Secondary outcomes

1

Description

Average days of hospitalization in ICU

Timepoint

Until discharge from the ICU

Method of measurement

days

2

Description

Day of hospitalization

Timepoint

Until discharge from hospital

Method of measurement

days

3

Description

Duration of intubation and Developing VAP,

Timepoint

Until developing of pneumonia

Method of measurement

days

4

Description

Duration of mechanical ventilation

Timepoint

Until being intubated

Method of measurement

days

5

Description

The frequency of clostridium difficile associated diarrhea

Timepoint

At the time of diarrhea

Method of measurement

Stool toxin

6

Description

The frequency of diarrhea associated with ICU

Timepoint

At the time of diarrhea

Method of measurement

Stool exam and exclude other causes

7

Description

Ventilator associated pneumonia complications

Timepoint

Daily

Method of measurement

Chest X-ray, blood tests and others

8

Description

Clinical status of patients (complete remission, partial remission, untreated, death)

Timepoint

Time of discharge from intensive care unit

Method of measurement

Clinical symptoms, chest x-ray, complications and other findings

Intervention groups

1

Description

Intervention group in addition to routine health care intervention for prevention of VAP getting Lactobacillus rhamnosus GG at a rate of 3×10^9 colony-forming units (cfu), 3 times a day (in the form of gavage)

Category

Treatment - Drugs

2

Description

Control group in addition to routine health care intervention for prevention of VAP getting placebo (Lactose-free milk AL110) 3 times a day (in the form of gavage)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Nader Zarinfar

Street address

Infectious Department, Vali-Asr Hospital, Vali-Asr Square, Arak, Iran

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Rafeie

Street address

Deputy of Research and Technology, Arak University of Medical Sciences, Basij Square, Arak, Iran

City

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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

Arak 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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Full name of responsible person

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Position

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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