Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 critria: 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 clostridim 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 geting Lactobacillus rhamnosus GG at a rate of 3 × 109 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 geting 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 Sqaure, Arak, Iran
City
Arak
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
Nader Zarinfar
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Person responsible for scientific inquiries

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Person responsible for updating data

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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