Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of probiotic on prevention of ventilator associated pneumonia in the patients admitted to ICU

Protocol summary

Summary

The aim of this randomized double blind clinical trial, the evaluation of efficacy of probiotic in prevention of ventilator associated pneumonitis in 164 patient admitted in ICU of rouhani hospital of Babol. Inclusion criteria: written consent from the family member; continuance of mechanical ventilation at least 72 hours; maximum 48 hours from intubation; start nutrition after 48 hours; no pneumonia; no tracheostomy Exclusion criteria: pregnancy; replacement of heart valve; vascular graft; history of rheumatoid fever; endocarditis; pancreatitis; fracture of base of skull; discharge less than one week. Intervention: Intervention group: the consumption of familact with the dose of 500 mg twice a day for 10 days. Control group: the consumption of placebo with the dose of 500 mg twice a day for 10 days. Patients are monitored for up to two weeks during mechanical ventilation and the incidence of pneumonia caused by mechanical ventilation is measured by a clinical evaluation of pulmonary infection that is measured every three days. In case of pneumonia the diagnosis was confirmed according to clinical pulmonary infection score. Primary outcome: prevention of ventilation associated pneumonitis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707227752N10**
Registration date: **2017-08-04, 1396/05/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-04, 1396/05/13

Registrant information

Name
Parviz Amri Maleh
Name of organization / entity
Babol University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Babol University Of Medical Sciences

Expected recruitment start date

2017-01-04, 1395/10/15

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotic on prevention of ventilator associated pneumonia in the patients admitted to ICU

Public title

The effect of probiotic on prevention of ventilator associated pneumonia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: written consent from the family member; continuance of mechanical ventilation at least 72 hours; maximum 48 hours from intubation; start

nutrition after 48 hours; no pneumonia; no tracheostomy Exclusion criteria: pregnancy; replacement of heart valve; vascular graft; history of rheumatoid fever; endocarditis; pancreatitis; fracture of base of skull; discharge less than one week.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **164**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The Patients are divided to a case and a control group according to Table of Random Numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Babol University Of Medical Sciences

Street address
Rouhani hospital, Ganjafrouz Street

City
Babol

Postal code
47176-41367

Approval date
2016-12-26, 1395/10/06

Ethics committee reference number
MUBABOL.REC.1395.198

Health conditions studied

1

Description of health condition studied
Ventilator associated pneumonia

ICD-10 code
J18

ICD-10 code description
Pneumonia, organism unspecified

Primary outcomes

1

Description
Ventilator associated pneumonia

Timepoint
3 days after intervention

Method of measurement
CPIS scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the consumption of familact with the dose of 500 mg twice a day.

Category
Prevention

2

Description
Control group: the consumption of placebo the the dose of 500 mg twice a days for 10 days.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Rouhani Hospital

Full name of responsible person
Mehdi Nasouhi

Street address
Rouhani Hospital, Ganjafrooz Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor research for Babol University of Medical Sciences

Full name of responsible person
Ali Bijani

Street address
Babol University Of Medical Sciences, Ganjafrooz street, Babol

City
Babol
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor research for Babol 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

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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