

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 1223 8296

##### Email address

pamrimaleh@mubabol.ac.ir

#### 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

**City**

Babol

**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

### Contact

**Name of organization / entity**  
Babol University of Medical Sciences

**Full name of responsible person**  
Parviz Amrimaleh

**Position**  
Associated Professor of Anesthesiology

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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Mahmoud Monadi

**Position**

Assistant Professor of Internal Department

**Other areas of specialty/work**

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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*