

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Evaluation of effects of probiotics on incidence of Ventilator Associated Pneumonia in Intensive Care Unit Patients

#### Protocol summary

##### Study aim

Effects of probiotics on the incidence of Ventilator-Associated Pneumonia in Intensive Care Unit Patients.

##### Design

A clinical trial with a control group, parallel groups, single blind, randomized, phase 3

##### Settings and conduct

Patients suffered from respiratory failure who has invasive airways who need mechanical ventilation in intensive care units randomly will be divided into two groups of intervention and control. In the intervention group, patients will take contents of Lactocare capsule via a naso-gastric tube. in the control group, patients will take contents of starch capsule via the naso-gastric tube as a placebo. Blinding: patients do not know the kind of prescribed drugs

##### Participants/Inclusion and exclusion criteria

Need to more than 48 hours of mechanical ventilation;  
No respiratory infection before initiation of mechanical ventilation; Need to invasive airways; No history or any sign and symptoms of any kind of immune deficiency.

##### Intervention groups

Intervention group: prescription of Lactocare capsule as a probiotic for evaluation of its effects on the reduction of incidence of ventilator-associated pneumonia  
Control group: prescription of the starch capsule as a placebo for comparison to the intervention group

##### Main outcome variables

Fever, leukocytosis, new lung infiltration in chest x-ray, signs of lung consolidation on auscultation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140129016415N7**

Registration date: **2019-12-03, 1398/09/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-03, 1398/09/12**

Update count: **0**

##### Registration date

2019-12-03, 1398/09/12

##### Registrant information

###### Name

Mohammad Golparvar

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3220 1750

###### Email address

golparvar@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-23, 1398/06/01

##### Expected recruitment end date

2020-03-19, 1398/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of effects of probiotics on incidence of Ventilator Associated Pneumonia in Intensive Care Unit Patients

##### Public title

evaluation effects of probiotics on ventilator associated pneumonia

##### Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Need to more than 48 hours of mechanical ventilation  
No respiratory infection before initiation of mechanical ventilation  
Need to invasive airways

### Exclusion criteria:

History or any sign and symptoms of any kind of immune deficiency

## Age

No age limit

## Gender

Both

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: **126**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization by computer-generated random numbers, patients according to the computer-generated random list will divide into the study and control group. (numbers lower than 0.5 in the study group and numbers greater than 0.5 in the control group).

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

No.100, Jahan-nama valley, Babalrahmeh street, Isfahan, Iran

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8136656433

#### Approval date

2017-06-16, 1396/03/26

#### Ethics committee reference number

IR.mui.REC.1396.3.261

## Health conditions studied

### 1

#### Description of health condition studied

Ventilator associated pneumonia

#### ICD-10 code

J18.9

#### ICD-10 code description

Pneumonia, unspecified

## Primary outcomes

### 1

#### Description

Pneumonia

#### Timepoint

Daily (at 8 AM) till end of mechanical ventilation

#### Method of measurement

Auscultation of lungs by stethoscope, measuring body temperature by thermometer, chest x ray

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Prescription of Lactocare Capsule, a mixed preparation of useful bacteria (lactobacils, Bifidobacils, Streptococcus), prepared by Zist Takhmir Pharmaceutical Company (Tehran-Iran), each 12 hours content of one capsule solve in 100 ml of water and gavage by nasogastric tube.

#### Category

Prevention

### 2

#### Description

Control group: Prescription of Placebo Capsule filled by starch, each 12 hours content of one capsule solve in 100 ml of water and gavage by nasogastric tube.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kashani Hospital

##### Full name of responsible person

Fereshteh Raufi

##### Street address

No.100, Jahan nama valley, Babalrahmeh street, Isfahn, Iran

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golparvar@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Dr Shaghayegh Haghjoo  
**Street address**  
No.4 Headquarters building, Isfahan university of  
Medical Sciences, hezarjarib Street, Isfahan, Iran  
**City**  
Isfahan  
**Province**  
Isfahan  
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8174673461  
**Phone**  
+98 31 3668 8138  
**Email**  
research@mui.ac.ir  
**Web page address**  
<https://research.mui.ac.ir/>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Esfahan University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Mohammad Golparvar  
**Position**

Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available