Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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

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Province

Isfehan

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

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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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
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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