Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Effect of probiotic preparation, lactocare, on incidence of ventilator associated pneumonia in critically ill patients

Protocol summary

Summary

The aim of the study is to determine effect of probiotic preparation, lactocare, on ventilator associated pneumonia incidence in the critically ill patients. After approval of the ethical committee of the university, 80 patients aging more than 80 years and undergoing mechanical ventilation will be enrolled in the study. An informed consent will be taken from the patients or their legal guardians to enter them in the study. All patients will receive standard treatment based on their disease. They will also receive assistance therapy. They will randomly be divided into two groups. The first group will receive standard and common treatment. They will also receive enteral Lactocare capsules every 12 hours. The second group will receive standard treatment plus placebo. The study will take on for a week. During this time, the vital signs and patient information (age, gender, number of aspiration per day, number of days under mechanical ventilation, mortality and APACHE II score will be recorded. All patients will have throat secretion at the beginning. Afterwards, it will be repeated twice during the study and after extubation. Throat secretion will be assessed by microbiological tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411182582N10**
Registration date: **2014-12-22, 1393/10/01**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-12-22, 1393/10/01

Registrant information

Name
Ata Mahmoodpoor
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-04-19, 1395/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotic preparation, lactocare, on incidence of ventilator associated pneumonia in critically ill patients

Public title

Effect of lactocare on pneumonia in critically ill patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion: patients aging more than 18 years old and needing mechanical ventilation for a period of more than 48 hours Exclusion: History of pneumonia; dissatisfaction

Age

From **18 years** old

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
Golgasht street
City
Tabriz
Postal code
Approval date
2010-09-20, 1389/06/29
Ethics committee reference number
Under evaluation

Health conditions studied

1

Description of health condition studied
pneumonia
ICD-10 code
J15.9
ICD-10 code description
Bacterial pneumonia, unspecified

Primary outcomes

1

Description
Ventilator Associated Pneumonia
Timepoint
7 days
Method of measurement
Assay with Clinically infectious pulmonary score and bronchoscopy

Secondary outcomes

1

Description
ICU length of stay
Timepoint
during ICU stay
Method of measurement
days that patient is stayed in ICU

Intervention groups

1

Description
All patients in control group will receive enteral capsules of placebo (1 capsule/12h) for one week in addition to standard VAP treatment.
Category
Placebo

2

Description
All patients in intervention group will receive enteral capsules of Lactocare (1 capsule/12h) for one week in addition to standard VAP treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada hospital ICU
Full name of responsible person
Ata Mahmoodpoor
Street address
Shohada hospital, El-goli street
City
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2

Recruitment center
Name of recruitment center
General ICU of Imam Reza hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research deputy of Tabriz University of Medical Sciences
Full name of responsible person
Mehdi Farhudi
Street address
Golgasht street
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research deputy of Tabriz 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
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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