

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

Country

Iran (Islamic Republic of)

Phone

+98 914 116 0888

Email address

mahmoodpoora@tbzmed.ac.ir

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

Tabriz

2**Recruitment center****Name of recruitment center**

General ICU of Imam Reza hospital

Full name of responsible person

Ata Mahmoodpoor

Street address

General ICU, Imam Reza hospital, Golgasht street

City

Tabriz

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

Name of organization / entity

Anesthesiology department, Tabriz University of Medical Sciences

Full name of responsible person

Ata Mahmoodpoor

Position

Director of ICU, Associate Professor

Other areas of specialty/work

Street address

Faculty of Medicine, Golgasht street

City

Tabriz

Postal code

Phone

+98 41 3332 8009

Fax

Email

mahmoodpoora@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Anesthesiology Department, Tabriz University of Medical Sciences

Full name of responsible person

Ata Mahmoodpoor

Position

ICU director, Associate Professor

Other areas of specialty/work

Street address

Faculty of Medicine, Golgasht street

City

Tabriz

Postal code

Phone

+98 41 3332 8009

Fax

Email

mahmoodpoora@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Anesthesiology Department, Tabriz University of Medical Sciences

Full name of responsible person

Roqhiye Asghari

Position

Anesthesiology resident

Other areas of specialty/work

Street address

Anesthesia department office, Faculty of Medicine, Golgasht street

City

Tabriz

Postal code

Phone

+98 41 3334 1994

Fax

Email

Dr.asghari80@yahoo.com

Web page address

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