

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of Probiotic capsule on Ventilator-Associated Pneumonia in patients hospitalized in Intensive Care Units of Poursina teaching remedial hospital of Rasht

Protocol summary

Study aim

The aim of this study was to investigate the effect of probiotic capsule consumption on the incidence of Ventilator-Associated Pneumonia in patients under mechanical ventilation admitted to intensive care units.

Design

The present study is a clinical trial study with a control group, triple blinds, parallel, phase 3 with a sample size of 92 people. Block randomization based on block permutation is used for randomization. To hide the allocation, block sizes are also randomly selected (4, 6). <https://www.sealedenvelope.com/> was used to generate a random allocation sequence.

Settings and conduct

The study sample is selected by available sampling method from mechanically ventilated patients admitted to the intensive care units of Poursina Hospital. The subjects, evaluators and analysts do not know the type of capsules.

Participants/Inclusion and exclusion criteria

Inclusion criteria: written informed consent from the client's family or guardian; age 18 years and older; under mechanical ventilation for more than 48 hours and more than 48 hours have passed since the intubation. Exclusion criteria: pregnancy at the time of admission; multiple organ dysfunction; pneumonia; chronic pulmonary disease; immunosuppressive diseases; immunosuppressive drug usage; stomach, esophagus and intestines damage and airway injury.

Intervention groups

Patients are divided into two groups: probiotics and placebo. Patients in the probiotic group receive Lactocare capsules (manufactured by Zist-Takhmir pharmaceutical company) and patients in the control group receive placebo capsules made by Zist-Takhmir companies. All patients receive routine nursing care prevention of Ventilator-Associated Pneumonia.

Main outcome variables

Incidence of Ventilator-Associated Pneumonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001174N13**

Registration date: **2021-02-16, 1399/11/28**

Registration timing: **prospective**

Last update: **2021-02-16, 1399/11/28**

Update count: **0**

Registration date

2021-02-16, 1399/11/28

Registrant information

Name

Atefeh Ghanbari

Name of organization / entity

Guilan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-10, 1400/01/21

Expected recruitment end date

2021-10-13, 1400/07/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Probiotic capsule on Ventilator-Associated Pneumonia in patients hospitalized in Intensive Care Units of Poursina teaching remedial hospital of Rasht

Public title

The effect of Probiotic capsule on Ventilator-Associated Pneumonia in patients hospitalized in Intensive Care Units

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Written informed consent from the client's family or guardian Age 18 years and older Under mechanical ventilation for more than 48 hours Not more than 48 hours have passed since the intubated

Exclusion criteria:

Pregnancy at the time of admission Multiple organ dysfunction History of Pneumonia Having chronic pulmonary disease Having immunosuppression diseases Immunosuppressive drug usage Stomach, esophagus and intestines damage Airway injury

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization based on block permutation is used for randomization. To hide the allocation, block sizes are also randomly selected (4, 6). If the patient leaves the study, the relevant patient code will be assigned to the new sample. The site <https://www.sealedenvelope.com/>, which was set up to randomize clinical trials, will be used to generate a random allocation sequence.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Study subjects are blind to the study intervention due to lack of knowledge about the type of drug (gavage as well as placebo or main drug). In the blinding of the evaluators, the ICU physician will not know about the randomization and the patient group to check the chest image and the final diagnosis of VAP, nor will the

coordinator and data collector (student) know about the patient group. The project supervisor is responsible for blinding other researchers and they will have access to all the information. The student and Statistics specialist, who is in charge of the final analysis of the project, are not aware of the type of intervention of the defined groups (probiotics or placebo) in SPSS software. The sample allocator to the groups is the student implementing the project. Due to the use of placebo in the project, the student who conducting the project will not be aware of the type of intervention performed in the groups. To hide the allocation, the size of the blocks is randomly selected (4, 6).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Guilan University Of Medical Science

Street address

Deputy of Research and Technology of Guilan University of Medical Sciences., In front of 17Sharivar Hospital., Shahid Siadati St., Namjoo Blvd.

City

Rasht

Province

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4146939114

Approval date

2021-01-27, 1399/11/08

Ethics committee reference number

IR.GUMS.REC.1399.552

Health conditions studied**1****Description of health condition studied**

Ventilator-Associated Pneumonia

ICD-10 code

J95.8

ICD-10 code description

Other postprocedural respiratory disorders

Primary outcomes**1****Description**

The incidence of Ventilator-Associated Pneumonia

Timepoint

All patients in both probiotic and placebo groups are monitored daily. Patients are monitored for Ventilator-Associated Pneumonia for up to 14 days after intubation and initiation of probiotic or placebo.

Method of measurement

The American College of Chest Physicians and ICD-10 criteria will be used to diagnose Ventilator-Associated Pneumonia in intubated patients admitted to intensive care units. These criteria; "Existence of new and continuous infiltration in the chest image with 2 or 3 cases: increase in temperature above 38.5 ° C or decrease in temperature below 35 ° C, increase in white blood cells above 12,000 per microliter, or a decrease in white blood cells to less than 3,000 per microliter, and purulent sputum are considered to indicate Ventilator-Associated Pneumonia. For microbiological diagnosis of ventilator-associated pneumonia, " Endotracheal Aspirate" culture will be used in a "quantitative" manner. In this method, a number of colonies above 100,000 is considered as a microbiological diagnosis of ventilator-dependent pneumonia.

Secondary outcomes

1

Description

Duration of mechanical ventilation

Timepoint

It is checked daily by the researcher.

Method of measurement

Researcher-made data collection form.

2

Description

Duration of hospitalization in the Intensive Care Unit

Timepoint

It is checked daily by the researcher.

Method of measurement

Researcher-made data collection form.

3

Description

Mortality rate

Timepoint

It is checked daily by the researcher.

Method of measurement

Researcher-made data collection form.

Intervention groups

1

Description

Intervention group: The subjects in the probiotic group receive Lactocare (manufactured by Zist-Takhmir Pharmaceutical Company) along with routine nursing care to prevent VAP. Each capsule Lactocare

(manufactured by Zist-Takhmir Pharmaceutical Company) contains ten to the power nine clones probiotic bacteria consisting of Lactobacillus rhamnosus, Lactobacillus helveticus, Lactobacillus casei, Lactobacillus acidophilus, Lactobacillus bulgaricus, Lactobacillus plantarum, Lactobacillus Gsry, Bifidobacterium bifidum, Bifidobacterium lactis, Bifidobacterium Breve, Bifidobacterium longum and Streptococcus thermophilus along with fructooligosaccharide (FOS) are used as prebiotics. The above capsule is administered to patients by gavage separately from the patient's diet formula with 20 cc of water, twice a day for a maximum of two weeks. Routine care for VAP prevention in this study includes mouthwash with chlorhexidine solution 4 times a day, raising the head and trunk 30 degrees, sterile suction if necessary, endotracheal tube cuff pressure control, standard nutritional gavage through nasopharyngeal tube. Prevention of gastric ulcer by using Stomach acid inhibitor and prevention of Deep Vein Thrombosis and hand hygiene by personnel.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group receive a placebo capsule made by Zist-Takhmir Company along with routine VAP nursing care. The placebo capsule (manufactured by Zist-Takhmir Pharmaceutical Company) contains starch, which is administered to patients by gavage separately from the patient's diet formula with 20 cc of water, twice a day for a maximum of two weeks. Routine care for VAP prevention in this study includes mouthwash with chlorhexidine solution 4 times a day, raising the head and trunk 30 degrees, sterile suction if necessary, endotracheal tube cuff pressure control, standard nutritional gavage through nasopharyngeal tube. Prevention of gastric ulcer by using Stomach acid inhibitor and prevention of Deep Vein Thrombosis and hand hygiene by personnel.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Educational & Remedial Center, Rasht

Full name of responsible person

Atefeh Ghanbari

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research and Technology of Guilan 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
Guilan University of Medical Sciences
Full name of responsible person
Atefeh Ghanbari
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Professor
Latest degree
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Main and total Data

When the data will become available and for how long

After publication the results, the access period begins

To whom data/document is available

Universities and scientific institutions

Under which criteria data/document could be used

In case of citing the article and observing the principles
of intellectual property

From where data/document is obtainable

Executor of proposal

What processes are involved for a request to access data/document

Contact with proposal executor and making ethical
agreement

Comments