

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Evaluation of the effect of symbiotic familact 2 plus on ventilator-associated pneumonia (VAP) in patients admitted to the intensive care unit

Protocol summary

Study aim

Determining and comparing the effect of symbiotic familact 2 plus on ventilator-associated pneumonia (VAP) in patients admitted to the intensive care unit

Design

The randomized, double-blind clinical trial, with the parallel groups, Phase 3 on 80 patients

Settings and conduct

This trial will be performed in Al-Zahra hospital in Isfahan. Patients will be given oral Familact 2 plus in the first group, and a placebo in the second group. The study is double-blind because the patients and the researcher will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria include hospitalization in the intensive care unit under mechanical ventilation, and informed consent to participate in the study. Exclusion criteria include pulmonary infection before the starting of mechanical ventilation.

Intervention groups

Intervention group: In this group, oral FamiLact synbiotic (probiotic + prebiotic) (Biology fermentation Company) 2 tablets daily every 12 hours will be prescribed. Control group In this group, 2 oral placebo drugs will be prescribed every 12 hours.

Main outcome variables

Duration of stay in ICU; Duration of connection to the ventilator; Incidence of pneumonia; Duration of pneumonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N45**
Registration date: **2021-10-20, 1400/07/28**

Registration timing: **prospective**

Last update: **2021-10-20, 1400/07/28**

Update count: **0**

Registration date

2021-10-20, 1400/07/28

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-03-22, 1401/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of symbiotic familact 2 plus on ventilator-associated pneumonia (VAP) in patients admitted to the intensive care unit

Public title

The effect of symbiotic familact 2 plus on ventilator-

associated pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalized in the intensive care unit under mechanical ventilation Satisfaction to participate in the study

Exclusion criteria:

Pulmonary infection before starting mechanical ventilation

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 80 eligible patients are randomly selected. For this, the letter A is written on 40 sheets, and the letter B is written on 40 sheets and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to observe blindness, the drugs are prepared in the same shape and amount before the intervention and are coded and given to the ICU nurse. They prescribe them without knowing the type of each drug. Therefore, the patient, the patient, the person recording the clinical and baseline information of the patients as well as the statistical analyst will not be aware of the type of intervention.

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

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfahan

Postal code

8179964167

Approval date

2020-11-26, 1399/09/06

Ethics committee reference number

IR.MUI.MED.REC.1399.756

Health conditions studied

1

Description of health condition studied

Pneumonia

ICD-10 code

J18

ICD-10 code description

Pneumonia, unspecified organism

Primary outcomes

1

Description

Incidence of pneumonia

Timepoint

Two weeks after the start of the intervention

Method of measurement

Based on the patient's symptoms and the result of sputum smear test

Secondary outcomes

1

Description

The length of stay in the ICU

Timepoint

Two weeks after the start of the intervention

Method of measurement

Record the number of days

2

Description

Duration of connection to the ventilator

Timepoint

Two weeks after the start of the intervention

Method of measurement

Record the number of days

Intervention groups

1

Description

Intervention group: In this group, oral FamiLact synbiotic (probiotic + prebiotic) (Biology fermentation Company) 2 tablets daily every 12 hours will be prescribed.

Category

Treatment - Drugs

2

Description

Control group: In this group, 2 oral placebo drugs will be prescribed every 12 hours.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Atousa Hakamifard

Street address

Department of Infectious Diseases and Tropical Medicine, Al-Zahra Hospital, Hezar Jarib Street.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

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Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Atousa Hakamifard

Position

Assistance professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

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Full name of responsible person

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Position

Non-faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available