

# 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.

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174673461

#### Phone

+98 31 3620 2020

#### Email

atousahakamifard@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Shaghayegh Haghjooy Javanmard

#### Street address

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

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174673461

#### Phone

+98 31 3668 8597

#### Email

dean@med.mui.ac.ir

### 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

#### Street address

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

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#### Province

Isfahan

#### Postal code

8174673461

#### Phone

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#### Email

atousahakamifard@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Atousa Hakamifard

#### Position

Assistant Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Infectious diseases

#### Street address

Department of Infectious Diseases and Tropical

Medicine, Al-Zahra Hospital, Hezar Jarib Street.

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**Email**

faranakkasiri9@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Faranak Kasiri

**Position**

Non-faculty specialist physician

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

**Street address**

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

**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