

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the effect of Familact synbiotic on the outcomes of the patients with community acquired pneumonia (clinical improvement, laboratory and complications)

Protocol summary

Study aim

Determination of the effect of Familact synbiotic on the outcomes of the patients with community acquired pneumonia (clinical improvement, laboratory and complications)

Design

Patients will be randomly divided into two groups using a random number table. One group will only be given antibiotics and the other group will be given antibiotics together with a capsule of synbiotic (Familact) daily for 10 days. All of the steps will be covered by the patient, physician and evaluators.

Settings and conduct

This prospective double-blind clinical trial study will be performed on the effect of Familact synbiotic in 130 patients over 18 years of age with community-acquired pneumonia admitted in the infectious ward of Vali-e-Asr Hospital in Birjand. Patients will be randomly divided into two groups using a random number table.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years old with community-acquired pneumonia diagnosed by an infectious disease specialist and requiring hospitalization (based on CURB-65 criteria), Patients with the same epidemiological factors (age, gender, and underlying disease) and possible microorganisms, Patients who need one type of treatment and do not need to other treatment such as steroids
Exclusion criteria: Patients who have taken antibiotics 48 hours before hospitalization, Patients with immunodeficiency (HIV, receiving immunosuppressive drugs, transplantation, chemotherapy, acute pancreatitis), pregnant and lactating women, Patients who have consumed probiotics, prebiotics and synbiotics in the past month, Patients who have not consented

Intervention groups

Intervention group: Familact capsule (once daily) for 10

days along with antibiotics
Control group: Only antibiotics

Main outcome variables

Fever; Respiratory rate; WBC; ESR; CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140623018206N2**

Registration date: **2021-07-14, 1400/04/23**

Registration timing: **prospective**

Last update: **2021-07-14, 1400/04/23**

Update count: **0**

Registration date

2021-07-14, 1400/04/23

Registrant information

Name

Azadeh Ebrahimzadeh

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Familact synbiotic on the outcomes of the patients with community acquired pneumonia (clinical improvement, laboratory and complications)

Public title

Evaluation of the effect of Familact synbiotic in treatment of community acquired pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients over 18 years old with community-acquired pneumonia diagnosed by an infectious disease specialist and requiring hospitalization (based on CURB-65 criteria) Patients with the same epidemiological factors (age, gender, and underlying disease) and possible microorganisms Patients who need one type of treatment and do not need to other treatment such as steroids

Exclusion criteria:

Patients who have taken antibiotics 48 hours before hospitalization Patients with immunodeficiency (HIV, receiving immunosuppressive drugs, transplantation, chemotherapy, acute pancreatitis), pregnant and lactating women Patients who have consumed probiotics, prebiotics and synbiotics in the past month Patients who have not consented

AgeFrom **18 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample sizeTarget sample size: **130****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients will be randomly divided into two groups using a random number table. In this way, first in Excel software, we create a variable from 1 to 130 (instead of 130, the total sample size). Then we create another variable in another column and generate 65 random numbers one and 65 random numbers two with the randomization command. The numbers of one are intervention group and the numbers of two groups are our placebo group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind. The patient and the executor (student) are not aware of the type of treatment each person receives. The tablets are designed in the same shape and in the same shape as the cans. Numbers 1 to 130 are written on dark envelopes and type A or B is placed inside the envelope. Envelopes are such that they will not be visible from the outside. In order, each person who opens the envelope will be opened in order and based on the A or B treatment, a can of A or B tablets will be given to the patient along with an explanation of how to use it.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Ghaffari Street

City

Birjand

Province

South Khorasan

Postal code

9718797187

Approval date

2019-11-30, 1398/09/09

Ethics committee reference number

IR.BUMS.REC.1398.264

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

community acquired pneumonia

ICD-10 code

J13

ICD-10 code description

Pneumonia due to Streptococcus pneumoniae

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

Fever

Timepoint

At first, after 72 hours, and at the end of hospitalization

Method of measurement

Thermometer

2

Description

Respiratory Rate

Timepoint

At first, after 72 hours, and at the end of hospitalization

Method of measurement

Respiratory Rate per minute

3

Description

White blood cells

Timepoint

After 72 hours of hospitalization

Method of measurement

Laboratory test

4

Description

Erythrocyte sedimentation rate

Timepoint

At first, and at the end of hospitalization

Method of measurement

Laboratory test

5

Description

C-Reactive Protein

Timepoint

At first, and at the end of hospitalization

Method of measurement

Laboratory test

Secondary outcomes

1

Description

Complications of pneumonia

Timepoint

At the end of study

Method of measurement

Questionnaire

2

Description

Duration of hospitalization

Timepoint

During the study

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Familact capsule (once daily) for 10 days along with antibiotics. Familact® is a synbiotic compound (probiotic + prebiotic) and it contains high amounts of 9 beneficial and safe bacterial strains along with fructooligosaccharide as a prebiotic. The strains and prebiotics used in this product include the following: Lactobacillus rhamnosus, bifidobacterium lactis, Lactobacillus casei, Bifidobacterium breve, Lactobacillus acidophilus, Bifidobacterium langum, Lactobacillus plantarum, Bifidobacterium bifidum and Streptococcus thermophilus.

Category

Treatment - Drugs

2

Description

Control group: Only antibiotics

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr Hospital

Full name of responsible person

Azadeh Ebrahimzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Azadeh Ebrahimzadeh

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available