Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Universtiy of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 1444 8671

Email address

a.ebrahimzadeh@bums.ac.ir

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
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target 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 Ebrahimzade
Street address
Vali Asr Hospital, Ghaffari Street
City
Birjand
Province
South Khorasan
Postal code
9718797187
Phone
+98 56 1444 8671
Email
A.ebrahimzadeh@bums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Tooba Kazemi
Street address
Birjand University of Medical Sciences, Ghaffari Street
City
Birjand
Province
South Khorasan
Postal code

9718797187

Phone
+98 56 3244 0388

Email
Drtooba.kazemi@gmail.com

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

Street address
Birjand University of Medical sciences, Ghaffari Street

City
Birjand

Province
South Khorasan

Postal code
9718797187

Phone
+98 56 1444 8671

Email
a.ebrahimzadeh@bums.ac.ir

Person responsible for scientific 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

Street address
Birjand University of Medical Sciences, Ghaffari Street

City
Birjand

Province
South Khorasan

Postal code
9718797187

Phone
+98 56 1444 7186

Email
a.ebrahimzadeh@bums.ac.ir

Person responsible for updating data

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

Street address
Birjand University of Medical Sciences, Ghaffari Street

City
Birjand

Province
South Khorasan

Postal code
9718797187

Phone
+98 56 1444 7186

Email
a.ebrahimzadeh@bums.ac.ir

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