

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of probiotic on improvement of pneumonia

Protocol summary

Study aim

The effect of probiotic on improvement of bacterial pneumonia in admitted patients to Shahid Beheshti hospital in Kashan Specific goals include: Determination of hospitalization duration, duration of dyspnea, tachypnea, cough, lung auscultation and reduction of fever in both groups.

Design

This study is a double-blind randomized clinical trial. Patients are randomly divided into case and control groups, each containing 50 patients.

Settings and conduct

Patients are randomly classified into two groups. Case group receive 2 sachets of probiotic /daily for 5 days and control group placebo. Patients in both groups receive same treatment protocol. This study is double blind randomized clinical trial. Probiotic and placebo are designed as medicinal sachets with same color and size. Numerical codes are recorded on each sachet from 1 to 100 and numbers for each group are determined using block randomization methods.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age over 12 years. 2. Early diagnosis is bacterial pneumonia. 3. Taking written consent from patients to entry the study. 4. The patient is able to eat probiotic or placebo. 5. Pneumonia is not very severe requiring admission in ICU. Exclusion criteria: 1. No previous heart failure and pulmonary edema. 2. No underlying pulmonary disease. 3. Intolerance or allergy to probiotic.

Intervention groups

All patients with bacterial pneumonia admitted to infectious and pediatric ward of Shahid Beheshti hospital in Kashan during 2018.

Main outcome variables

The probiotic can be effective in reducing the duration of dyspnea, tachypnea, cough, fever and length of hospitalization.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200107046047N1**

Registration date: **2020-04-07, 1399/01/19**

Registration timing: **retrospective**

Last update: **2020-04-07, 1399/01/19**

Update count: **0**

Registration date

2020-04-07, 1399/01/19

Registrant information

Name

Ahmad Najafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5533 0489

Email address

najafi-a@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-30, 1396/11/10

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

2018-01-30, 1396/11/10

Actual recruitment end date

2018-04-19, 1397/01/30

Trial completion date

2018-04-24, 1397/02/04

Scientific title

The effect of probiotic on improvement of pneumonia

Public title

Probiotic in treatment of pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 12 years. Bacterial pneumonia is early diagnosis. Taking written consent from the patient to participate in the study. The patient is able to eat probiotic or placebo. Pneumonia is not very severe requiring admission in ICU.

Exclusion criteria:

The patient has no previous heart failure and pulmonary edema. No underlying pulmonary disease. Intolerance or allergy to probiotic. Dissatisfaction of patients for participating in study.

Age

From **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

We divide each referral into two groups using a randomized table. This table is a collection of number. Consider numbers from 1 to 50 for intervention and numbers 51 to 100 for control . The lets move on one of the numbers and move in one of the preset directions and assign the numbers to one of the groups. Thus patients are completely randomly divided.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, principal investigator, clinical caregivers

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kashan University of Medical

Sciences

Street address

Third floor, Zagros building, Baran street, Shohada fin bozorg bulvard, Amerieh square, Amir Kabir street

City

Kashan

Province

Isfahan

Postal code

8718615699

Approval date

2018-01-29, 1396/11/09

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1396.101

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

Bacterial pneumonia

ICD-10 code

J15

ICD-10 code description

Bacterial pneumonia, not elsewhere classified

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

Duration of hospitalization

Timepoint

From hospitalization to discharge

Method of measurement

Number of days of hospitalization based on patient file and questionnaire

2**Description**

Dyspnea duration

Timepoint

From hospitalization to discharge

Method of measurement

Completion of questionnaire and examination of patient

3**Description**

Tachypnea duration

Timepoint

From hospitalization to discharge

Method of measurement

Completion of questionnaire and examination of patient

4**Description**

Duration of cough

Timepoint

From hospitalization to discharge

Method of measurement

Completion of questionnaire and examination of patient

5**Description**

Duration of lung auscultation rales

Timepoint

From hospitalization to discharge

Method of measurement

Patient examination and questionnaire completion

6**Description**

Duration of fever

Timepoint

From hospitalization to discharge

Method of measurement

Patient examination and questionnaire completion

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Two sachets of probiotic daily for 5 days, product of Biology fermentation company

Category

Treatment - Drugs

2**Description**

Control group: Two sachets of placebo daily for 5 days, product of Farabi company

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Beheshti hospital of Kashan

Full name of responsible person

Dr Ahmad Najafi

Street address

Shahid Beheshti hospital, Ravandi boulevard

City

Kashan

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Email

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Web page address

http://Beheshti.Kaums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Dr Hamidreza Benafsheh

Street address

Deputy of research and technology, Kashan

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Email

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Web page address

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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

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Dr Ahmad Najafi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Dr Ahmad Najafi

Position

Resident

Latest degree

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Web page address**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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Journal file in website of deputy of research and
technology of Kashan Medical Sciences

When the data will become available and for how long

since 2020

To whom data/document is available

Universities of Medical Science

Under which criteria data/document could be used

for the purpose of scientific exploitation

From where data/document is obtainable

Journal file in website of deputy of research and
technology of Kashan Medical Sciences

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

Search of journal title in website of deputy of research
and technology of Kashan Medical Sciences

Comments