

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

An Investigation of the Effect of Using Synbiotic and Zinc in the Treatment of Admitted Children with Bacterial Pneumonia

Protocol summary

Study aim

Evaluation of the interventional effects of probiotics and zinc sulfate on clinical symptoms and duration of Hospitalization in children with bacterial pneumonia

Design

Clinical trial study includes control and invention groups, randomized block blocking method, double blind. The sample size in each group is 45 person, and a total of 135 patients. Describe quantitative variables with mean and standard deviation and for qualitative variables with a large percentage. ANOVA tests are used to compare means.

Settings and conduct

Double-blind clinical trial. Heshmatieh hospital of Sabzevar university of medical sciences. Prescription antibiotics is the basis of treatment similarly in all three groups. Prescription age-based synbiotics Pedilact and Kidilact in the second group and zinc sulfate syrup in the third group. Blindness: The patient was randomly assigned to study in one of three groups and uninformed about the type of intervention group by treatment evaluator.

Participants/Inclusion and exclusion criteria

Criteria for entry: Infants and children aged 1 month to 18 years, based on clinical, radiographic, and laboratory findings, including: leukocytosis with left shifting, high erythrocyte sedimentation rate, high C-reactive protein, or pulmonary involvement in chest radiography. Criteria for no entry: The presence of underlying disease includes: cystic fibrosis, congenital heart disease, immunodeficiency, chronic pulmonary heart disease, neuro developmental delay and Failure to Thrive(FTT).

Intervention groups

Control group: antibiotic treatment alone, Prescribing antibiotics, along with the synbiotics, Prescribing antibiotics, along with zinc sulfate syrup

Main outcome variables

Number of hospitalization days, fever, respiratory rate, retraction, crackle, wheezing, coughing, and side effects

such as diarrhea at the time of entry and during days of hospitalization.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190611043869N1**

Registration date: **2020-05-23, 1399/03/03**

Registration timing: **retrospective**

Last update: **2020-05-23, 1399/03/03**

Update count: **0**

Registration date

2020-05-23, 1399/03/03

Registrant information

Name

Sara Binesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4466 1777

Email address

bineshs96@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

2019-12-02, 1398/09/11

Actual recruitment end date

2020-03-19, 1398/12/29

Trial completion date

2020-03-19, 1398/12/29

Scientific title

An Investigation of the Effect of Using Synbiotic and Zinc in the Treatment of Admitted Children with Bacterial Pneumonia

Public title

An Investigation of the Interventional Effect of Using Probiotics and Zinc in the Treatment of Admitted Children with Bacterial Pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Infants and children aged 1 months up to 18 years if diagnosed on medium to very severe bacterial pneumonia Shift left-sided leukocytosis, or Erythrocyte Sedimentation Rate(ESR) and C- Reactive Protein(CRP), or pulmonary involvement in radiography (Basis of clinical, radiographic, and laboratory findings from the Integrated Management of Childhood Illness (IMCI) and Nelson 2016).

Exclusion criteria:

Cystic fibrosis, maternal coronary heart disease, immunodeficiency, chronic heart disease, developmental delay, and Failure to Thrive(FTT) (weight for age below the 3rd percentile). Parental dissatisfaction

Age

From **1 month** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **135**

Actual sample size reached: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization does not guarantee balance in numbers in the study. Especially, if patient characteristics change over time (for example, early patients are worse after treatment) in the early imbalance can not be corrected. Randomization the block is used to solve this problem. The main idea of randomized block division patients to M block 2N, so that in each block N patient A and N patient B is assigned. The block is then randomly selected. This B to the method of allocating equal treatment in each block provided that the block is fully utilized $2 \times 2 =$ and the block size is 4 B, A, ensures, for example: two treatments assignment of treatment may be within each block (6) BAAB, (5) ABBA, (4) BABA, (3) ABAB, (1) AABB (2) BBAA

The size of the block, depending on the number of treatments, should be short enough to balance prevent, and be large enough to guess the allocation of treatment in each prevent the group during the study. The size of the block should be at least 2 times the number of groups be a cure. The size of the block is not stated in the study so that researchers are blind to it. If the blocks are expressed, the therapeutic series in each block are predictable. For example, 2 N it can be inferred. This can be B as A and in B it should be A, = in block 4 This is a way to prevent this error (Selection bias) That is: 1. The mechanism of the block should not be revealed 2. The use of random block size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This research is a double-blind clinical trial in which concealment is performed on the person allocating the treatment so that the patient is selected and the type of intervention group is determined randomly and without the knowledge of the person allocating the treatment. The person evaluating the treatment also does not know the type of drug assigned to the groups. To evaluate the outcome, patients' clinical symptoms at first entry and daily until the discharge through examination, is evaluated by a person who is not aware of the type of treatment assigned and is recorded in the relevant table.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences. Asadabadi Ave., Sabzevar, Iran

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873119

Approval date

2019-09-24, 1398/07/02

Ethics committee reference number

IR.MEDSAB.REC.1398.072

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

Temperature

Timepoint

Daily during Hospitalization

Method of measurement

Thermometer

2

Description

Respiration Rate

Timepoint

Daily during Hospitalization

Method of measurement

Cornometer

3

Description

Cough

Timepoint

Daily during hospitalization

Method of measurement

Physical Examination

4

Description

Crackle

Timepoint

Daily during hospitalization

Method of measurement

Physical Examination

5

Description

Wheezing

Timepoint

Daily during hospitalization

Method of measurement

Physical Examination

6

Description

Tachypnea

Timepoint

Daily during hospitalization

Method of measurement

Physical Examination

7

Description

Subcostal, Intercostal, Suprasternal Retraction

Timepoint

Daily during Hospitalization

Method of measurement

Physical Examination

8

Description

Nasal Flaring

Timepoint

Daily during hospitalization

Method of measurement

Physical Examination

Secondary outcomes

1

Description

Diarrhea

Timepoint

Daily during hospitalization

Method of measurement

Observation

Intervention groups

1

Description

Control group: Antibiotic treatment alone. The type of antibiotic used and the duration of treatment are determined based on the severity of the pneumonia based on the Integrated Management of Childhood Illness (IMCI) approach and Nelson 2016, and vary from a minimum of 5 to 7 days, up to a maximum of 14 days. The mentioned antibiotic treatment protocol is also implemented in the second and third intervention groups.

Category

Treatment - Drugs

2

Description

Intervention group 1: prescribing antibiotics (similar to the first group), along with the antibiotic. The type, amount, and method of use of Sinbiotic varies depending on the age of the child. PediLact oral drops for children under two years of age are used at a daily rate of 5 drops for 5 days. For children over 2 years of age, KidiLact is used daily for 1 day for 5 days, mixed with water, juice, milk or baby food, and taken 2 to 4 hours after antibiotic administration (Water, milk or food should not be too hot). KidiLact contains high amounts of 7 strains of probiotic bacteria, including the specific probiotic strain

in children "Bifido bacterium infantis", along with the prebiotic fructooligosaccharide.

Category

Treatment - Drugs

3**Description**

Intervention group 2: Prescribing antibiotics (similar to the first group), along with zinc sulfate syrup. The dose is 10 mg zinc sulfate per day for children under 1 year of age and 20 mg per day for children over 1 year of age for 5 days.

Category

Treatment - Drugs

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

Heshmatieh Hospital

Full name of responsible person

Dr Morteza Rasti sani

Street address

Pediatric Section, Heshmatie Hospital, Asadabadi Ave., Sabzevar, Iran.

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873119

Phone

+98 51 4401 1600

Fax

+98 51 4423 8718

Email

info@medsab.ac.ir

Web page address

http://medsab.ac.ir

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

Sabzevar University of Medical Sciences

Full name of responsible person

Dr Ali Reza Moslem

Street address

Sabzevar University of Medical Sciences, Asadabadi Ave., Sabzevar, Iran.

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 1000

Email

info@medsab.ac.ir

Web page address

http://www.medsab.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sabzevar 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**

Sabzevar University of Medical Sciences

Full name of responsible person

Sara Binesh

Position

Pediatric Assistant

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Pediatric Section, Heshmatie Hospital, Asadabadi Ave., Sabzevar, Iran.

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4466 1777

Fax**Email**

sara76.binesh@gmail.com

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

Sabzevar University of Medical Sciences

Full name of responsible person

Sara Binesh

Position

Pediatric Assistant

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Pediatric Section, Heshmatie Hospital, Asad Abadi Ave., Sabzevar, Iran.

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4466 1777

Fax**Email**

sara76.binesh@gmail.com

+98 51 4466 1777

Fax**Email**

sara76.binesh@gmail.com

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data Files, Statistical analysis, Article, Thesis, Questionnaires.

When the data will become available and for how long

No limit

To whom data/document is available

Students and Researchers

Under which criteria data/document could be used

Submitting a letter of introduction from a university or research institute

From where data/document is obtainable

Dr Sara Binesh, Pediatric Assistant, Sabzevar University of Medical Sciences. Pediatric Section, Heshmatie Hospital, Asadabadi Ave., Sabzevar, Iran. Postal Code: 9613873136 Tell: 051440111606 Mobile: 09155722137 E. mail: sara76.binesh@gmail.com

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

Email to researcher: sara76.binesh@gmail.com

Correspondence to researcher.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Sara Binesh

Position

Pediatric Assistant

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Pediatric Section, Heshmatie Hospital, Asadabadi Ave., Sabzevar, Iran.

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone