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)

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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 are 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 × 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

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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 infentis", 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

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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

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

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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
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Comments