Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Zinc and Vitamin D supplementation on Acute Bronchiolitis in 2 to 23 months old children, a clinical trial

Protocol summary

Study aim
The comparison of the effect of Zinc and Vitamin D supplementation on Acute Bronchiolitis

Design
In this research, 135 eligible patients suffering from Acute Bronchiolitis were chosen purposefully. Then, patients were randomly divided into control and intervention groups.

Settings and conduct
In this double blind research,135 children who are at the age of 2 to 23 months and who are admitted in Mousavi Hospital in Zanjan with the diagnosis of Acute Bronchiolitis will be chosen randomly. These children will be divided into three blind groups and they will evaluate blindly. First group takes Zinc, second takes Vitamin D, and third takes no supplement.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age under 2 years old; The first wheezing attack with respiratory infection; Pulse Rate less than 180; Respiratory Rate less than 100 Exclusion criteria: Use of supplementary more than routine; Previous wheezing or use of bronchodilator; Prematurity Cardiopulmonary disease; Aspiration; Neuromuscular disease; Immune deficiency; Need for mechanical ventilation; Previous use of corticostroid in 2 last weeks; Intolerancy or cuasing side effects after using the medicine

Intervention groups
In three groups; First group takes Hypertonic Salin and Zinc Sulfate(20 mg) every day for a week, Second group takes HypertonicSalin and Vitamin D(100 unit per kg)every day for a week, And third group just takes Hypertonic Salin.

Main outcome variables
Studing of the duration of fever; Staying in the hospital; Respiratory distress; Respiratory rate; Wheezing; Saturation of oxygen; And granting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131217015835N7**
Registration date: **2018-05-17, 1397/02/27**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-17, 1397/02/27**
Update count: **0**

Registration date
2018-05-17, 1397/02/27

Registrant information

Name
Parisa Khoshnevisasl

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 24 1427 2737

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khoshnevis@zums.ac.ir

Recruitment status
Recruitment complete

Funding source
zanjan university of medical sciences ,vice chancellor for research

Expected recruitment start date
2017-09-27, 1396/07/05

Expected recruitment end date
2018-06-20, 1397/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Zinc and Vitamin D supplementation on Acute Bronchiolitis in 2 to 23 months old children, a clinical trial

Public title
Comparison of the effect of Zinc and Vitamin D supplementation on Acute Bronchiolitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age under 2 years old The first wheezing attack with respiratory infection Pulse Rate less than 180 Respiratory Rate less than 100

Exclusion criteria:
Use of supplementary more than routine Previous wheezing or use of bronchodilator Prematurity Cardiopulmonary disease Aspiration Neuromuscular disease Immune deficiency Need for mechanical ventilation Previous use of corticostroid in 2 last weeks Intolerancy or cuasing side effects after using the medicine

Age
From **2 months** old to **23 months** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **135**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple and individual randomization is chosen. Random number table is used. We will use numbers from 1 to 135 in this table and we will read these numbers from up to down and we will write the succession. Then we will give Vitamin D to numbers 1 to 45 and Zinc to numbers 46 to 90 and no drugs to numbers 91 to 135. Then for allocation concealment we will use sequentially numbered, sealed, opaque envelopes. Every one who will enter our study will chose one envelope which has one number of the table in it and the group will be chosen for that person.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this trial participants and the outcome evaluators are blind. Participants know that they take supplements besides routine drugs but instead of the name of the supplements we use codes. The evaluators evaluate the outcomes according to the codes.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics commite of zanjan university of medical sciences

Street address
zanjan university of medical sciences ,azadi square

City
Zanjan

Province
Zanjan

Postal code
45154

Approval date
2017-07-23, 1396/05/01

Ethics committee reference number
zums.rec.1396.50

Health conditions studied

1

Description of health condition studied
Acute bronchiolitis

ICD-10 code
J21.9

ICD-10 code description
Acute bronchiolitis, unspecified

Primary outcomes

1

Description
wheezing

Timepoint
first day,third day,and seventh day in the hospital

Method of measurement
using stethoscope

2

Description
respiratory rate

Timepoint
first day,third day,and seventh day in the hospital

Method of measurement
counting of chest movements

Secondary outcomes

1

Description
the duration of staying in the hospital

Timepoint
first day,third day,seventh day
Method of measurement
counting the days of staying in the hospital

2

Description
the duration of fever
Timepoint
first day,third day,seventh day
Method of measurement
thermometer

3

Description
percent of arterial saturation of oxygen
Timepoint
first day,third day,seventh day
Method of measurement
pulseoxymeter

4

Description
the duration of existence of cough
Timepoint
first day,third day.seventh day
Method of measurement
asking from the patient

5

Description
side effects of drugs
Timepoint
first day,third day,seventh day
Method of measurement
asking from the patient and physical examination

6

Description
the duration of cyanosis
Timepoint
first day,third day,seventh day
Method of measurement
observe the color of skin

7

Description
the duration of respiratoty distress
Timepoint
first day,third day,seventh day
Method of measurement
observe useing of respiratory muscles which are not the main ones

8

Description
the duration of dehydration
Timepoint
first day,third day,seventh day
Method of measurement
amount of urine out put and mucusal dryness and skin turgor

Intervention groups

1

Description
Intervention group: First group takes 2 mg/kg/day(max 20 mg) syrup Zinc Sulfate10 of Alhavy Company for 1 week or during hospitalization if the days of admission are less than 1 week.
Category
Treatment - Drugs

2

Description
Intervention group: Second group takes 100 unit per kg per day drop Vitamin D (1000 IU in 1 ml) of Vitabiotic company for 1 week or during hospitalization if the days of admission are less than 1 week.
Category
Treatment - Drugs

3

Description
Control group: Third group does not take any supplements.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Musavi Hospital
Full name of responsible person
Dr. Parisa Khoshnevis Asl(pediatrics specialist)
Street address
Musavi Hospital, Gavazan Blvd., Zanjan
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Zanjan
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Zanjan
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4513956183
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Email
Mousavihospital@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Chancellor of Research and Technology, Zanjan University of Medical Sciences (Primary sponsor)

Full name of responsible person
Dr. Alireza Shoghli

Street address
Zanjan University of Medical Sciences, Azadi square, Zanjan, Iran

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Zanjan

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45154

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+98 24 3342 0651

Email
shoghli@zums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Chancellor of Research and Technology, Zanjan University of Medical Sciences (Primary sponsor)

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
Zanjan University of Medical Sciences

Full name of responsible person
Dr. Parisa Khoshnevis Asl

Position
Pediatrician

Latest degree
Specialist

Other areas of specialty/work

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Pediatrics department, Ayatollah Moussavi Hospital, Gavazang street, Zanjan, Iran

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Position
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Person responsible for updating data

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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