

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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 causing 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 Hypertonic Salin 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)

Phone

+98 24 1427 2737

Email address

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 causing 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 zanzan university of medical sciences

Street address

zanzan university of medical sciences ,azadi square

City

Zanzan

Province

Zanzan

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 respiratory distress

Timepoint

first day,third day,seventh day

Method of measurement

observe use 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 output and mucosal 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., Zanzan

City

Zanzan

Province

Zanzan

Postal code

4513956183

Phone

+98 24 3313 0000

Email

Mousavihospital@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Chancellor of Research and Technology, Zanzan University of Medical Sciences (Primary sponsor)

Full name of responsible person

Dr. Alireza Shoghli

Street address

Zanzan University of Medical Sciences, Azadi square, Zanzan, Iran

City

Zanzan

Province

Zanzan

Postal code

45154

Phone

+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, Zanzan 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**

Zanzan University of Medical Sciences

Full name of responsible person

Dr. Parisa Khoshnevis Asl

Position

Pediatrician

Latest degree

Specialist

Other areas of specialty/work**Street address**

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

City

Zanzan

Province

Zanzan

Postal code

4513956183

Phone

+98 24 3313 0000

Fax**Email**

khoshnevis@zums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Zanzan University of Medical Sciences

Full name of responsible person

Dr. Parisa Khoshnevis Asl

Position

Pediatrician

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Other areas of specialty/work**Street address**

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Phone

+98 24 3313 0000

Fax**Email**

khoshnevis@zums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Zanzan University of Medical Sciences

Full name of responsible person

Dr. Parisa Khoshnevis Asl

Position

Pediatrician

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+98 24 3313 0000

Fax**Email**

khoshnevis@zums.ac.ir

Web page address

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