Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the effect of Zinc gluconate and placebo in the treatment of tachypnea, dyspnea and fever in children aged 2-23 months with acute bronchiolitis

Protocol summary

Study aim
The objective of this randomized, double-blind clinical trial is evaluation of effect of zinc gluconate in the treatment of children aged between 2-23 months with acute bronchiolitis.

Design
In this double-blind randomized controlled clinical trial with a parallel group, 100 children with acute bronchiolitis will be divided into two groups randomly.

Settings and conduct
In this double-blind study, personal information's, clinical signs and symptoms and laboratory findings of the patients will be recorded in prearranged forms at the time of admission. Zinc gluconate 1% syrup will be prescribed for the case group and a placebo solution will be prescribed for the control group . Clinical signs and symptoms of patients such as coryza, cough, fever, tachypnea, etc were recorded at 0, 24, 72 hours and 7 days after the beginning of the treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: being at the age of 2 to 23 months; first episode of wheezing following the viral infection of the upper respiratory tract; presence of clinical manifestations of acute bronchiolitis; absence of consolidation on the chest x-ray. Exclusion criteria: patients with history of more than one episode of wheezing; history of asthma and allergy in the patients and their family; congenital heart disease; malnutrition and pneumonia; low birth weight and intrauterine growth retardation (IUGR); previous antibiotic therapy.

Intervention groups
Intervention group: Zinc gluconate 1% syrup, Control group: Placebo solution. children younger than 1 year of age will receive 10 mg Zinc gluconate 1% or placebo solution in two divided doses and those over the age of 1 year will receive 20 mg in two divided doses. The drugs will be administered for 5 days.

Main outcome variables
Tachypnea; dyspnea; fever

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160318027097N12**
Registration date: **2018-11-28, 1397/09/07**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-28, 1397/09/07**
Update count: **0**

Registration date
2018-11-28, 1397/09/07

Registrant information
Name
Dr Faramarz Darghahi
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-11-22, 1397/09/01
Expected recruitment end date
2019-03-20, 1397/12/29
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Zinc gluconate and placebo in the treatment of tachypnea, dyspnea and fever in children aged 2-23 months with acute bronchiolitis

Public title

Effect of zinc gluconate on acute bronchiolitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 2 to 23 months First episode of wheezing following the viral infection of the upper respiratory tract Presence of clinical manifestations of acute bronchiolitis Absence of consolidation on the chest x-ray

Exclusion criteria:

patients with history of more than one episode of wheezing history of asthma and allergy in the patients and their family congenital heart disease malnutrition low birth weight previous antibiotic therapy pneumonia intrauterine growth retardation (IUGR)

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who will admitted on odd days will be assigned into intervention group and patients who will admitted on even days will be assigned into control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, participants and researchers are unaware of the type of prescribed drugs for the groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardebil University of Medical Sciences

Street address

Ardabil University of Medical Sciences, Daneshgah Avenue

City

Ardabil

Province

Ardabil

Postal code

5163639888

Approval date

2018-10-31, 1397/08/09

Ethics committee reference number

IR.ARUMS.REC.1397.097

Health conditions studied

1

Description of health condition studied

Acute bronchiolitis

ICD-10 code

J21

ICD-10 code description

Acute bronchiolitis

Primary outcomes

1

Description

Tachypnea

Timepoint

Before the intervention; 24 hours, 72 hours and 7 days after the intervention

Method of measurement

Clinical examinations

2

Description

Dyspnea

Timepoint

Before the intervention; 24 hours, 72 hours and 7 days after the intervention

Method of measurement

Clinical examinations

3

Description

Fever

Timepoint

Before the intervention; 24 hours, 72 hours and 7 days after the intervention

Method of measurement

Clinical examinations

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: prescribing syrup Zinc gluconate 1%; produced by Simorgh Darou Attar Company, for 5 days; children younger than 1 year of age will receive 10 mg in two divided doses and those over the age of 1 year will receive 20 mg in two divided doses.
Category
Treatment - Drugs

2

Description
Control group: prescribing Placebo; produced by Simorgh Darou Attar Company, for 5 days; children younger than 1 year of age will receive 10 mg in two divided doses and those over the age of 1 year will receive 20 mg in two divided doses.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Boali hospital
Full name of responsible person
Maryam Rihaniyan
Street address
Boali hospital, Daneshgah Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Dr Manochehr Barak
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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
Ardabil 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
Ardabil University of Medical Sciences
Full name of responsible person
Dr Adel Ahadi
Position
Associate professor
Latest degree
Specialist
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Other areas of specialty/work
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Person responsible for updating data

Contact
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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
Yes - There is a plan to make this available
Title and more details about the data/document
Total potential data after making individuals data unidentifiable
When the data will become available and for how long
Start the access period from 2021
To whom data/document is available
Researchers at academic and scientific institutions
Under which criteria data/document could be used
Data can be used for scientific and research studies.
From where data/document is obtainable
Maryam Rihaniyan; Medical student; Naghizadeh73@yahoo.com
What processes are involved for a request to access data/document
After receiving the request email, data files will be sent in less than a week.
Comments