

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 2000

Email address

mj.naghizadeh@arums.ac.ir

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

Ardebil University of Medical Sciences, Daneshgah Avenue

City

Ardebil

Province

Ardebil

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

City

Ardabil

Province

Ardabil

Postal code

5163639888

Phone

+98 45 3351 2000

Email

Naghizadeh73@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr Manochehr Barak

Street address

Boali hospital, Daneshgah Avenue

City

Ardabil

Province

Ardabil

Postal code

5163639888

Phone

+98 45 3351 2006

Email

Naghizadeh73@yahoo.com

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

Other areas of specialty/work

Pediatrics

Street address

Boali hospital, Daneshgah Avenue

City

Ardabil

Province

Ardabil

Postal code

5163639888

Phone

+98 45 3351 2000

Email

Naghizadeh73@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr Manochehr Barak

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Boali hospital, Daneshgah Avenue

City

Ardabil

Province

Ardabil

Postal code

5163639888

Phone

+98 45 3351 2006

Email

M.barak@arums.ac.ir

5163639888

Phone

+98 45 3351 2006

Email

Naghizadeh73@yahoo.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

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

Ardabil University of Medical Sciences

Full name of responsible person

Maryam Rihaniyan

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Boali hospital, Daneshgah Avenue

City

Ardabil

Province

Ardabil

Postal code