

# 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**