

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Efficacy of zinc as adjuvant therapy in the treatment of pneumonia in hospitalized children aged 2 months to 5 years in 17 Shahrivar Training Hospital of Rasht- Iran

Protocol summary

Summary

Study objective: To determine the efficacy of zinc as adjuvant therapy in the treatment of pneumonia in hospitalized children aged 2 months to 5 years in 17 Shahrivar Training Hospital of Rasht- Iran. Study Design: Randomized, double-blind, placebo-controlled trial. Study population: children 2 months to 5 years old hospitalized for pneumonia in hospital in 17 Shahrivar Training Hospital of Rasht- Iran. Main inclusion criteria: children 2 months to 5 years old hospitalized in 17 Shahrivar Hospital of Rasht - Iran with fever (axillary temperature 37.5° C or more) and cough and tachypnea or rales. Main exclusion criteria: the history of pulmonary disease including asthma, documented heart disease or other chronic disease or immunodeficiency, proven pathologic gastroesophageal reflux disorder, malnutrition or growth failure, and treatment with zinc or a zinc supplement within 3 months past. Sample size: 120 patients (60 patients in each group) Study intervention (s) and time of this: After obtaining informed consent from the parents, all the patients' basic necessary information including patient demographics, admission temperature and respiratory rate are taken and recorded. The patient will enter to one of two groups, zinc or placebo therapy, by fixed block method method. Nurses shall prescribe oral zinc to the first group and placebo to the second group. The standard treatment will be conducted for both groups includes antibiotics prescription. A resident who is unaware of the adjuvant treatment, will follow the patients for response to treatment. Study outcomes: the primary outcome is normalization of patient's body temperature and respiratory rate. Secondary outcome is hospital discharge or death.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305072438N2**

Registration date: **2013-08-04, 1392/05/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-08-04, 1392/05/13

Registrant information

Name

Houman Hashemian

Name of organization / entity

Guilan University of medical sciences- Medical faculty- 17 Shahrivar hospital

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 9061

Email address

hashemian@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Guilan University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-06-21, 1393/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of zinc as adjuvant therapy in the treatment of pneumonia in hospitalized children aged 2 months to 5 years in 17 Shahrivar Training Hospital of Rasht- Iran

Public title

Efficacy of zinc in the treatment of children with pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children 2 months to 5 years old hospitalized in 17 Shahrivar Hospital of Rasht - Iran with fever (axillary temperature 37.5° C or more) and cough and tachypnea or rales. Exclusion criteria: the history of pulmonary disease including asthma, documented heart disease or other chronic disease or immunodeficiency, proven pathologic gastroesophageal reflux disorder, malnutrition or growth failure, and treatment with zinc or a zinc supplement within 3 months past.

Age

To 5 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences- Vice Chancellor for Research

Street address

Namjoo St.- Rasht- Guilan- Iran

City

Rasht

Postal code

Approval date

2013-04-20, 1392/01/31

Ethics committee reference number

9210029702

Health conditions studied

1

Description of health condition studied

Pneumonia

ICD-10 code

J18.9

ICD-10 code description

Pneumonia, unspecified

Primary outcomes

1

Description

Fever subsidence

Timepoint

Daily during hospitalization

Method of measurement

Degrees Centigrade (axillary method with a mercury thermometer)

2

Description

normalization of patient's respiratory rate

Timepoint

Daily during hospitalization

Method of measurement

The number of breaths per minute (patient observation by pediatric resident)

Secondary outcomes

1

Description

Hospital discharge or death

Timepoint

Daily during hospitalization

Method of measurement

By pediatric resident

Intervention groups

1

Description

Intervention group: oral zinc (zinc sulfate syrup by mouth or gavage) of 20 mg daily for children 12 months and more and 10 mg daily for children less than 12 months, for 7 days

Category

Treatment - Drugs

2

Description

Control group: Placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
17 Shahrivar Pediatric Training Hospital
Full name of responsible person
Dr. Houman Hashemian
Street address
17 Shahrivar Pediatric Training Hospital- Namjoo St.-
Rasht
City
Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Guilan University of Medical Sciences- Vice Chancellor
for Research
Full name of responsible person
Dr. Abdolrasool Sobhani
Street address
Vice Chancellor for Research- Shahid Beheshti St.-
Gaz Ave.- Rasht
City
Rasht
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes

Title of funding source
Guilan University of Medical Sciences- Vice Chancellor for
Research
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Dr. Houman Hashemian
Position

Pediatric Infectious Diseases Subspecialist-Assistant
Professor

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty