

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Zinc effect on treatment of Pneumonia in pediatric patients (3- 60 mo) admitted in Abuzar hospital in 1388

Protocol summary

Summary

According to different effects of zinc supplements, this study was designed to determine the therapeutic impacts of zinc supplementation to current therapy of pneumonia. In this study, all 3 to 60 months old children admitted in Abuzar hospital with the diagnosis of pneumonia were included. The clinical criteria for diagnosis of pneumonia in a child with cough and breathing problems were: a) Tachypnea: respiratory rate over 45/minutes on the age of 3 months to 6 months and more than 40/minutes in the age of 6 months to one year and more than 30/minutes in the age of 12 months to 60 months; b) Fever: the high temperature of 38.5 rectal; c) Symptoms of respiratory distress. Exclusion criteria: a) malnutrition, b) Symptoms of systemic diseases, c) Diarrhea, d) Known intolerance or allergy to zinc or zinc containing drugs. Studied population consisted of 128 patients (64 individuals receiving zinc supplement and 64 placebos). In this study we evaluated the impact of additional zinc supplement and/or placebo to the conventional therapy, on clinical symptoms and duration of hospitalization.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810303122N1**

Registration date: **2010-03-29, 1389/01/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-03-29, 1389/01/09

Registrant information

Name

Ehsan Valavi

Name of organization / entity

Ahvaz Jundishapur University

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Jundishapur university

Expected recruitment start date

2009-01-20, 1387/11/01

Expected recruitment end date

2010-01-21, 1388/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Zinc effect on treatment of Pneumonia in pediatric patients (3- 60 mo) admitted in Abuzar hospital in 1388

Public title

The impact of zinc supplement on treatment of pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) age of 3 to 60 mo, 2) Clinical diagnosis of pneumonia: a) Tachypnea: > 45 in 3-6mo, >40 in 6-12mo, >30 in 13-36mo, >25 in 37-60mo b) Fever: >38.5 Rectal c) Respiratory distress: Nasal flaring, intercostals retraction, Central cyanosis d) Rales in chest

auscultation e) Infiltration in Chest X ray, 3) Parents satisfaction, 4) The ability of child to drink the drug and placebo Exclusion criteria: 1) Malnutrition, 2) Additional systemic disease (meningitis, sepsis), 3) Diarrhea (> 3 time watery defecations), 4) Allergy to zinc supplements, 5) Severe respiratory disease, family history of asthma, congenital heart disease, 6) Chest wheezing in physical examination, 7) History of recently using antibiotic

Age

From **1 year** old to **4 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **128**

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**

Ethics committee of Ahvaz Jundishapur university of medical sciences

Street address

Golestan St.

City

Ahvaz

Postal code**Approval date**

empty

Ethics committee reference number

8/20/1458/پ

Health conditions studied**1****Description of health condition studied**

Pneumonia

ICD-10 code

J18

ICD-10 code description

Pneumonia, organism unspecifide

Primary outcomes**1****Description**

Fever improvement

Timepoint

every 4 hr

Method of measurement

Termometer

2**Description**

Tachypnea improvement

Timepoint

every 4 hr

Method of measurement

Breathing rate

Secondary outcomes**1****Description**

Duration of Hospitalization

Timepoint

on discharge time

Method of measurement

Days from admission

Intervention groups**1****Description**

adding Zinc suplement to the conventional drugs: 2 mg/kg

Category

Treatment - Drugs

2**Description**

adding placebo to the conventional drugs

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Abuzar Hospital

Full name of responsible person

Ehsan Valavi

Street address**City**

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Jundishapur university

Full name of responsible person

Mostafa Fegghi

Street address

Golestan St.

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Jundishapur university

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

Jundishapur university

Full name of responsible person

Ehsan Valavi

Position

Assistant prof.

Other areas of specialty/work

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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