

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

“Effect of oral supplementation of zinc on treatment of otitis media with effusion”

Protocol summary

Summary

The object of this study was to determine the effect of oral zinc sulfate supplementation given with coamoxiclav as compared with coamoxiclav alone for treatment of otitis media with effusion (OME). The efficacy was assessed 3 and 6 weeks after administration. In a double - blind, randomized trial a total of 52 children with OME who referred to ear, nose and throat clinic were randomly assigned into two groups. Patients treated with coamoxiclav plus zinc sulfate syrup 100 mg per 100ml, 10ml daily for 3 weeks in zinc group and placebo in control group. Treatment repeated for patients who have not been treated after 3 weeks (total of 6 weeks). Treatment were assessed by otoscopy and tympanometry in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809292893N1**

Registration date: **2007-03-20, 1385/12/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2007-03-20, 1385/12/29

Registrant information

Name

Poopak Izadi

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 9437

Email address

izadi@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahed University

Expected recruitment start date

2007-03-20, 1385/12/29

Expected recruitment end date

2008-03-19, 1386/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

“Effect of oral supplementation of zinc on treatment of otitis media with effusion”

Public title

“Effect of oral supplementation of zinc on treatment of otitis media with effusion”

Purpose

Treatment

Inclusion/Exclusion criteria

Patients were excluded if they had any of the followings: ruptured tympanic membrane and otorrhea, a history of hypersensitivity to penicillin or zinc derivatives, antimicrobial treatment in the preceding 30 days, diseases such as sinusitis or pneumonia or anemia, recent episode of acute otitis media, previous adenoidectomy or ventilation tube insertion, compromised immunity or any pathology of the ear, nose and throat or factors that could preclude completion of treatment

Age

To **15 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 52

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 Shahed University

Street address

Tehran qom highway, In front of holy shrine of Imam Khomeini

City

Tehran

Postal code

Approval date

empty

Ethics committee reference number

37824

Health conditions studied

1

Description of health condition studied

Otitis Media with effusion

ICD-10 code

H65.9, H65

ICD-10 code description

Nonsuppurative otitis media, unspecified

Primary outcomes

1

Description

Tympanic membrane status

Timepoint

baseline, 3 weeks, 6 weeks

Method of measurement

examination

Secondary outcomes

empty

Intervention groups

1

Description

Coamoxiclav suspension, 312, 5mg/5cc, 40mg/kg/day (TDS), oral + Placebo syrup, 10 ml daily, 3 and 6 weeks, oral

Category

Placebo

2

Description

Coamoxiclav suspension, 312, 5mg/5cc, 40mg/kg/day (TDS), oral +zinc sulfate syrup,100ml, 10ml daily(equal to 10 mg zinc), 3 and 6 weeks, oral

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mostafa Khomeini hospital

Full name of responsible person

Street address

Tehran qom highway, Shahed university

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Poopak Izadi

Street address

Shahid Mostafa Khomeini hospital,Italia ave.,Keshavarz Blvd.,Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed 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

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Person responsible for general inquiries

Contact

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Poopak Izadi
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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