Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Zinc Supplement on the Clinical Symptoms and Spirometry in Children with Moderate Asthmatic Disease

Protocol summary

Summary

This is a randomized, double blind, placebo-control trial study in 300 children with asthma. We use placebo (sugar) in control group and Zinc Sulfate (50 mg/daily) in intervention group for 8 weeks. All of them have FEV1 less than 80% (moderate Asthma). We do Spirometry before and after treatment. Also we check CBC with Diff for Eosinophilia and total IgE. At Least, we evaluate Effect of Zinc Sulfate on the Spirometry and Clinical Manifestation. Inclusion Criteria: Age Between 5-17 years old, Asthma more than 1 Year, FEV1 <80%. Exclusion criteria: heart, kidney, liver and thyroid diseases; normal Spirometry; recent pneumonia and sinusitis; intake of Vitamins or Trace elements.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105316660N1**
Registration date: **2011-07-20, 1390/04/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-07-20, 1390/04/29

Registrant information

Name

Javad Ghafari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3326 0054

Email address

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Zinc Supplement on the Clinical Symptoms and Spirometry in Children with Moderate Asthmatic Disease

Public title

Effect of Zinc Supplement on Children with Asthmatic Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 5-17 years old; asthma more than 1 year; FEV1 <80%. Exclusion criteria: heart, kidney, liver and thyroid diseases; normal spirometry; recent pneumonia and sinusitis; intake of Vitamins or Trace elements.

Age

From **5 years** old to **17 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size
Target sample size: **300**
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
Mazandaran University of Medical Sciences
Street address
Moallem Square
City
Sari
Postal code
Approval date
2010-11-24, 1389/09/03
Ethics committee reference number
89-104

Health conditions studied

1

Description of health condition studied
Asthmatic Patients
ICD-10 code
J45
ICD-10 code description
Asthma

Primary outcomes

1

Description
clinical manifestation of asthma
Timepoint
8 weeks
Method of measurement
observation

2

Description
Spirometry
Timepoint
8 Weeks
Method of measurement
Spirometer

Secondary outcomes

1

Description
Eosinophil
Timepoint
8 weeks
Method of measurement
laboratory test

2

Description
Total IgE
Timepoint
8 Weeks
Method of measurement
Labratory Test

Intervention groups

1

Description
Zinc Sulfte (50 mg/Daily)
Category
Treatment - Drugs

2

Description
Placebo (Suger) for 8 Weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Toba Clinic of Sari
Full name of responsible person
Dr Javad Ghafari
Street address
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person

Dr Ahmadali Enayati

Street address

No.2 Biulding, Mazandaran University of Medical Sciences, Moallem Square

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran University of Medical Sciences

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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Javad Ghafari

Position

Alergist and Clinical Immunologist, Associate Professor

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