

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

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##### 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.

##### 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

#### 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

##### 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 Building, 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**

Allergist 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*