

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effect of zinc supplementation on the frequency and duration of colds in children aged 6 to 10 years

#### Protocol summary

##### Study aim

Determining the effect of zinc supplementation on the frequency and duration of colds in 6- to 10-year-old children

##### Design

One group will receive zinc sulfate supplements for 10 days and the other group will receive a placebo. Then, in the next visit or follow-up by phone, the duration of each of the symptoms of runny nose and stuffy nose, cough, sneezing, fever, and the overall duration of the disease will be examined in both groups. The information obtained by Naram Statistical analysis software and the results are reported in the form of a thesis.

##### Settings and conduct

in affiliated hospitals of Tehran Islamic Azad University of Medical Sciences during the years 1401-1402. 25 people in each group are included in the study. Each patient is assigned a number and randomly placed in two groups according to the online random numbers table. Due to the double-blindness of this study, the drugs used for the patients at the beginning of the study are A/B by the head of the department so that the researcher and the participants do not know the type of drug received.

##### Participants/Inclusion and exclusion criteria

Age 6-10 years Not suffering from an underlying disease such as type 1 diabetes, thyroid disorders, heart disorders, etc. Not taking chronic medication such as corticosteroids

##### Intervention groups

One group will receive zinc sulfate supplements for 10 days and the other group will receive a placebo. Then, in the next visit or follow-up by phone, the duration of each of the symptoms of runny nose and stuffy nose, cough, sneezing, fever and the overall duration of the disease will be investigated in both groups.

##### Main outcome variables

duration of cold Number of colds

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230902059330N1**

Registration date: **2023-09-14, 1402/06/23**

Registration timing: **retrospective**

Last update: **2023-09-14, 1402/06/23**

Update count: **0**

##### Registration date

2023-09-14, 1402/06/23

##### Registrant information

##### Name

Mohammad mehdi Zareie

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2264 2269

##### Email address

2emehdii@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-21, 1402/01/01

##### Expected recruitment end date

2023-08-23, 1402/06/01

##### Actual recruitment start date

2023-03-21, 1402/01/01

##### Actual recruitment end date

2023-08-23, 1402/06/01

##### Trial completion date

2023-08-23, 1402/06/01

##### Scientific title

Investigating the effect of zinc supplementation on the frequency and duration of colds in children aged 6 to 10 years

#### Public title

Investigating the effect of zinc supplementation on the frequency and duration of colds in children aged 6 to 10 years

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

6-10 years old no underlying disease such as type 1 diabetes, thyroid disorders, heart disorders, etc. no chronic medication such as corticosteroids

##### Exclusion criteria:

Lack of parental consent to participate in the study Lack of access to the patient to follow up on treatment results

#### Age

From **6 years** old to **10 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

- Participant
- Care provider

#### Sample size

Target sample size: **50**

Actual sample size reached: **50**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

50 patients are included in the study. Each patient is assigned a number and the patients are randomized according to the online random number table and are placed in two groups (A, intervention and control).

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Due to the double-blindness of this study, the drugs used for the patients are divided by the head of the department in the form of A/B at the beginning of the study so that the researcher and the participants do not know the type of drug received. In this study, both the patient and the doctor did not know which group the patient was in. After the end of the study, according to the patient coding table at the beginning of the study, the placement of each patient in each group (intervention/control) is determined.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tehran Islamic Azad University of Medical Sciences

##### Street address

Headquarters building of Tehran Islamic Azad University of Medical Sciences, corner of Gol Ikh St., Aineh Blvd., Amir Pabarja St., Doktor Shariati St., Doktor Shariati St., Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1949635881

#### Approval date

2023-01-01, 1401/10/11

#### Ethics committee reference number

IR.IAU.TMU.REC.1401.321

## Health conditions studied

### 1

#### Description of health condition studied

Cold

#### ICD-10 code

J12.8

#### ICD-10 code description

Other viral pneumonia

## Primary outcomes

### 1

#### Description

duration of cold

#### Timepoint

10 days after the start of the study

#### Method of measurement

Interview and examination

### 2

#### Description

Number of colds

#### Timepoint

10 days after the start of the study

#### Method of measurement

Interview and examination

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: zinc sulfate supplement 5 mg. Construction of the country of Iran. Razak Laboratories Co. Patients in the intervention group will receive the syrup for 10 days (they should consume 5-8 ml every day). This syrup contains 23% zinc as an element.

### Category

Treatment - Drugs

## 2

### Description

Control group: receives a placebo

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

affiliated hospitals of Tehran Islamic Azad University of Medical Sciences

#### Full name of responsible person

Mohammad Mehdi Zarei

#### Street address

Headquarters building of Tehran Islamic Azad University of Medical Sciences, corner of Gol Ikh St., Aineh Blvd., Amir Pabarja St., Doktor Shariati St., Doktor Shariati St., Tehran

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#### Postal code

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#### Phone

+98 21 2660 2642

#### Email

2emehdii@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Dr. Majid Naqipour

#### Street address

Headquarters building of Tehran Islamic Azad University of Medical Sciences, corner of Gol Ikh St., Aineh Blvd., Amir Pabarja St., Doktor Shariati St., Doktor Shariati St., Tehran

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#### Phone

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#### Email

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#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Islamic Azad University

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Mohammad Mehdi Zarei

#### Position

student

#### Latest degree

Medical doctor

#### Other areas of specialty/work

General Practitioner

#### Street address

Headquarters building of Tehran Islamic Azad University of Medical Sciences, corner of Gol Ikh St., Aineh Blvd., Amir Pabarja St., Doktor Shariati St., Doktor Shariati St., Tehran

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#### Phone

+98 21 2660 2642

#### Email

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Mohammad Mehdi Zarei

**Position**

student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Public Health

**Street address**

Headquarters building of Tehran Islamic Azad University of Medical Sciences, corner of Gol Ikh St., Aineh Blvd., Amir Pabarja St., Doktor Shariati St., Doktor Shariati St., Tehran

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**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Mohammad Mehdi Zarei

**Position**

student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Public Health

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable