Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr. Majid Naqipour

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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

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Person responsible for scientific inquiries

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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