

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Assessment of etiologic factors of anorexia, and the frequency of using zinc supplements in preschool children referred to Pediatric clinics affiliated to Isfahan University of Medical Sciences in 2013, and determination of the effects of zinc on improving their appetite

Protocol summary

Summary

1.Objectives:In developing countries,reduced calorie intake can cause delay in growth and development of children. Growth delay is an important reason that can cause cognitive problems in children.this problem not only play an important role in children's talent but can improve immunity of these children.It seems that in our society, unnecessary zinc supplement is used in a wide spectrum.The goals are to determine prevalence of kinds of food behavior in children and organic reasons (anemia,...)and the relation between kind of behaviors and anorexia patterns and frequency of zinc supplement usage and level of Zn, mg and iron and mean of micro and macro nutrients and mean of calories and anorexia pattern before and after drug and placebo usage.

2.Design:This survey is designed first to analyze the etiologic factors of anorexia in preschool children and also analysis of zinc effect in this regard. 3.Setting and conduct:This survey is in two parts: first, children aged between 2 to 6 years will be studied and their mothers will be interviewed to fill in a questionnaire; then in part two, in a triple masked study, 48 cases and 48 controls will be selected. 4.Participants including major eligibility criteria:Inclusion criteria : age 2 to 6 y ;chief complaint of anorexia; not having any disability;not using any supplementation. Exclusion criteria: low compliance of family, dislike of children to use drug or placebo; gastrointestinal complications in the group receiving zinc . 5.interventions: The case group will receive 10 mg of zinc syrup for 3 months and control groups that uses placebo for 3 months. 6. The main outcome measures are: changes in children food behavior, frequency of iron,zinc,or magnesium deficiencies,intake of calories, protein,carbohydrate and fat

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302061434N7**

Registration date: **2013-05-01, 1392/02/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-01, 1392/02/11

Registrant information

Name

Roya Kelishadi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 3060

Email address

kelishadi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences, Thesis.

Expected recruitment start date

2013-02-08, 1391/11/20

Expected recruitment end date

2014-01-20, 1392/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Assessment of etiologic factors of anorexia, and the frequency of using zin supplements in preschool children referred to Pediatric clinics affiliated to Isfahan University of Medical Sciences in 2013, and determination of the effects of zinc on improving their appetite

Public title
Assessment of etiologic factors of anorexia, and the frequency of using zin supplements in preschool children referred to Pediatric clinics affiliated to Isfahan University of Medical Sciences in 2013, and determination of the effects of zinc on improving their appetite

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion/exclusion criteria : age 2 to 6 y old;c.c of loss of appetite;loss of disabillity;not using any supplementation ;not distribution ;dislike to use drug or plassebo; GI complication

Age
From **2 years** old to **6 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of faculty of Medicine, Isfahan University of Medical Sciences

Street address
Hezarjerb Ave

City
Isfaahan

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
111111

Health conditions studied

1

Description of health condition studied
Anorexia in preschool children

ICD-10 code
R63.0

ICD-10 code description
Loss of appetite

Primary outcomes

1

Description
children food behavior

Timepoint
at the beginnig and 3 months after

Method of measurement
questionnaire CEBQ

2

Description
organic reasons

Timepoint
at the beginnig

Method of measurement
Labratory

3

Description
zn mg iron

Timepoint
at the beginnig and 3 months after

Method of measurement
labratory

Secondary outcomes

1

Description
height

Timepoint
at the beginnig and 3 months after

Method of measurement

cm

2

Description

anorexia criteria

Timepoint

at the beginnig and 3 months later

Method of measurement

questionnaire

3

Description

calorie intake

Timepoint

at the beginnig and 3 months after

Method of measurement

questionnaire

Intervention groups

1

Description

The case group receive zinc sulfate syrup for 3 months, name of substance:zinc sulfate, chemical constant: zinc sulfate. chemical constant:syrup/usage:daily/dosage:5 cc/ time of usage:3 months

Category

Treatment - Drugs

2

Description

The control group receive placebo similar to zinc sulfate syrup for 3 months .name of substance: placebo/chemical constant:syrup/usage:daily/dosage:5 cc/ time of usage:3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan university clinics

Full name of responsible person

Pediatric clinics affiliated to Isfahan University of Medical Sciences

Street address

Pediatric clinics, Imam Hossein Hospital, Imam Khomeini St.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Isfahan University of Medical Sciences

Full name of responsible person

Peyman Adibi

Street address

Isfahan university of medical science.Hezarjerib Ave
.Isfahan

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Dr Roya Kelishadi/Dr Majid Khademian/Dr Neda Farhangpajhoo

Position

MD,Professor/MD,Assistant Professor /MD,Resident

Other areas of specialty/work

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Contact

Name of organization / entity

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Full name of responsible person

Dr Roya Kelishadi/Dr Majid Khademian/Dr Neda Farhangpajhoo

Position

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Web page address**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

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

Isfahan university of medical science

Full name of responsible person

Dr Roya Kelishadi/Dr Majid Khademian/Dr Neda Farhangpajhoo

Position

MD/MD/MD