

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Evaluating the effect of snack fortified with vitamin D, iron, zinc and arginine compared with conventional snack on the anthropometric indices of malnourished children

#### Protocol summary

##### Study aim

Determination of the effect of snack fortified with vitamin D, iron, zinc and arginine on the growth indices of malnourished children.

##### Design

Two-arm, parallel group, double blind, randomized (using blocked randomization) controlled trial

##### Settings and conduct

This study was conducted in elementary boys' school in Shiraz. Following selection of qualified individuals, the complete study process was explained to the parents and written informed consent was obtained. All subjects entered to a 2-week run-in period before intervention to obtain detailed information about the dietary intakes and physical activity. At the end of run-in period participants were randomly assigned to receive either 1 servings/day (2200 ml/day) of fortified snack or 1 servings/day (200 ml/day) of conventional snack for 90 days.

Anthropometric indices and biochemical assessment were done at the beginning and at the end of the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: aged between 6 and 10 years; Children with a weight for age chart below the 5th percentile; Children whose parents have completed the informed consent form; Non inclusion criteria: Serious medical illnesses including neurological, cancer, thyroid, cardiovascular, gastrointestinal, endocrine, renal, hepatic and eating disorders; Intake of medications that could affect body weight, appetite, vitamin D, zinc and iron metabolism

##### Intervention groups

Control group: receiving snack without fortification.  
Intervention group: receiving snack fortified with arginine, zinc, iron, vitamin D.

##### Main outcome variables

Weight for age

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181204041843N1**

Registration date: **2019-01-25, 1397/11/05**

Registration timing: **retrospective**

Last update: **2019-01-25, 1397/11/05**

Update count: **0**

##### Registration date

2019-01-25, 1397/11/05

##### Registrant information

##### Name

Seyed Mohammad Aqaiezhad Rudbane

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3725 1001

##### Email address

aqaeinezhad@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-21, 1397/06/30

##### Expected recruitment end date

2019-01-05, 1397/10/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluating the effect of snack fortified with vitamin D, iron, zinc and arginine compared with conventional snack on the anthropometric indices of malnourished children

## Public title

The effect of snacks fortified with vitamin D, iron, zinc and L-arginine on malnutrition

## Purpose

Other

## Inclusion/Exclusion criteria

### Inclusion criteria:

Aged between 6 and 10 years Children with a weight for age chart below the 5th percentile Children whose parents have completed the informed consent form

### Exclusion criteria:

Serious medical illnesses including neurologic, cancer, thyroid, cardiovascular, gastrointestinal, endocrine, renal, hepatic and eating disorders Children with long-term short stature Intake of medications that could affect body weight, appetite, vitamin D, zinc and iron metabolism Participation in any other weight management studies within the last 6 months Taking multivitamin-mineral supplements and other food supplements

## Age

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

## Gender

Male

## Phase

N/A

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Participants are randomly allocated into two groups of control and intervention using blocked randomization.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participants and investigators will be blinded by the use of the same-shape package of snacks to both groups

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

Ethics committee

## Name of ethics committee

Ethical Committee of the Shiraz University of Medical Sciences

## Street address

Central building of Shiraz University of Medical Sciences, Zand street

## City

Shiraz

## Province

Fars

## Postal code

71348-14336

## Approval date

2018-01-16, 1396/10/26

## Ethics committee reference number

IR.SUMS.REC.1396.163

## Health conditions studied

### 1

#### Description of health condition studied

Malnutrition

#### ICD-10 code

E44

#### ICD-10 code description

Protein-calorie malnutrition of moderate and mild degree

## Primary outcomes

### 1

#### Description

Weight for age

#### Timepoint

Before intervention, after intervention

#### Method of measurement

Digital scale

## Secondary outcomes

### 1

#### Description

25 (OH)vit D

#### Timepoint

Before intervention, after intervention

#### Method of measurement

ELISA

### 2

#### Description

Serum Ferritin

#### Timepoint

Before intervention, after intervention

#### Method of measurement

ELISA

### 3

Description

Serum iron  
**Timepoint**  
Before intervention, after intervention  
**Method of measurement**  
Spectrophotometry

#### 4

**Description**  
Albumin  
**Timepoint**  
Before intervention, after intervention  
**Method of measurement**  
Laboratory measurement

#### 5

**Description**  
Serum transferrin  
**Timepoint**  
Before intervention, after intervention  
**Method of measurement**  
Laboratory measurement

#### 6

**Description**  
Serum Zinc  
**Timepoint**  
Before intervention, after intervention  
**Method of measurement**  
Laboratory measurement

#### 7

**Description**  
Serum IGF-1  
**Timepoint**  
Before intervention, after intervention  
**Method of measurement**  
Laboratory measurement

#### 8

**Description**  
Anthropometric indices (weight, Height, BMI)  
**Timepoint**  
Before intervention, after intervention  
**Method of measurement**  
Digital scales

### **Intervention groups**

#### 1

**Description**  
Intervention group: Daily intake of 200 ml of dairy snack fortified with 5 g of arginine, 4 g of zinc, 4 g of iron and 500 units of vitamin D for 90 days.  
**Category**  
Treatment - Other

#### 2

**Description**  
Control group: Daily intake of 200 ml of regular snack (no fortification) for 90 days.  
**Category**  
Treatment - Other

### **Recruitment centers**

#### 1

**Recruitment center**  
**Name of recruitment center**  
Elementary Schools in Shiraz  
**Full name of responsible person**  
Seyed Mohammad Aqaiezhad  
**Street address**  
Department of Education in Shiraz, East Moadel street  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7134785475  
**Phone**  
+98 71 3233 5953  
**Email**  
farsmedu@gmail.com

### **Sponsors / Funding sources**

#### 1

**Sponsor**  
**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr. Zohreh Mostafavipour (Vice Chancellor for Education, Shiraz University of Medical Sciences)  
**Street address**  
Shiraz University of Medical Sciences, Zand St.  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7134814336  
**Phone**  
+98 71 3233 2093  
**Email**  
madopzsh@sums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shiraz University of Medical Sciences  
**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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Seyed Mohammad Aqaiezhad

**Position**

Ph.D. Candidate of Nutrition Sciences

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

School of Nutrition and Food Sciences, Razi Blvd.

**City**

Shiraz

**Province**

Fars

**Postal code**

71645-111

**Phone**

+98 71 3725 1001

**Email**

aqaeinezhad@sums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Siavash Babajafari

**Position**

Assistant Professor in Nutrition Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

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

Shiraz University of Medical Sciences

**Full name of responsible person**

Seyed Mohammad Aqaiezhad

**Position**

Ph.D. Candidate in Nutrition Sciences

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

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**Postal code**

71645-111

**Phone**

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**Email**

aqaeinezhad@sums.ac.ir

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no program for its release

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available