

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The Effect of milk consumption in breakfast on satiety and energy intake in 10-12 years old obese children

#### Protocol summary

##### Summary

Current study will be a randomized cross-over clinical trial. 20 children aged 10 to 12 y will be enrolled based on the inclusion criteria. They will randomly be divided into three intervention groups (breakfast with low-fat milk, juice or water). Each intervention period will last 2 consecutive days. A group of Children will consume a breakfast including 240 mL low-fat milk, children in the second group will receive 240 mL apple juice and children in third group will receive same volume of water (Energy for the first and second group and the composition of breakfast for all groups will be the same). One serving of fruit (similar in 3 groups) will be given to children as a snack during all intervention days. Intervention periods will be one week apart as a wash-out period. Visual analog scale (VAS) test for satiety will be used before each snack and lunch to assess the participant's appetite before receiving each meal or snack, throughout intervention days. An ad libitum lunch will be provided for all participants to assess differences in energy intake after each intervention. Appetite and energy intake of children from snacks, lunch and rest of the day will be compared between 3 beverages.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013022312571N1**

Registration date: **2013-12-02, 1392/09/11**

Registration timing: **na**

Last update:

Update count: **0**

##### Registration date

2013-12-02, 1392/09/11

##### Registrant information

##### Name

Amin Salehi-Abargouei

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3820 9100

##### Email address

abargouei@hlth.mui.ac.ir

##### Recruitment status

**Not enough for processing**

##### Funding source

1. Vice Chancellor for Research, Isfahan University of Medical Sciences, Isfahan, Iran. 2. Food security research center, Isfahan University of Medical Sciences, Isfahan, Iran.

##### Expected recruitment start date

2013-11-05, 1392/08/14

##### Expected recruitment end date

2013-01-18, 1391/10/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of milk consumption in breakfast on satiety and energy intake in 10-12 years old obese children

##### Public title

The effect of dairy consumption on energy intake and appetite

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: being obese based on WHO criteria (having a BMI above the 95th percentile based on BMI-

for-age charts); not on a special diet and do not intend to go on diet during the study; children and their parents intend to be entered in the study; not having any cow milk intolerance; not having any history of congenital or metabolic diseases based on information provided by parents and consuming breakfast regularly. Exclusion criteria: low cooperation (Refusing to participate in at least two of the interventions; Desire to withdraw from the study for any reason)

**Age**

From **10 years** old to **12 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **20**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Isfahan Regional Bioethics Committee

**Street address**

Isfahan University of Medical Sciences, Hezarjarib St.,

Isfahan

**City**

Isfahan

**Postal code**

81745319

**Approval date**

2013-02-13, 1391/11/25

**Ethics committee reference number**

392165

**Health conditions studied****1****Description of health condition studied**

obesity

**ICD-10 code**

E66.0

**ICD-10 code description**

Obesity due to excess calories

**Primary outcomes****1****Description**

energy intake

**Timepoint**

one time at lunch meal

**Method of measurement**

Analysis of food intake at lunch

**2****Description**

appetite

**Timepoint**

Five times per hour after intervention

**Method of measurement**

Visual analog scale for satiety

**Secondary outcomes****1****Description**

weight

**Timepoint**

Four times: at baseline and before the start of each period of intervention

**Method of measurement**

Using a digital scale with minimal wear

**Intervention groups****1****Description**

intervention: Including 240 ml low-fat milk in breakfast

**Category**

Other

**2****Description**

control: Including 240 ml apple juice in breakfast

**Category**

Other

**3****Description**

control: Including 240 ml water in breakfast

**Category**

Other

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

One of the elementary schools in the 4th educational district of Isfahan

**Full name of responsible person**

Sanaz Mehrabani

**Street address**

Isfahan, Asgarie street, next to the Arash park, hasane jafarian school

**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**

Dr.Peyman.Adibi

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib Street, 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****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*

### 2

**Sponsor****Name of organization / entity**

Food security research center

**Full name of responsible person**

Dr Leila Azadbakht

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan

**City**

Isfahan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

Yes

**Title of funding source**

Food security research center

**Proportion provided by this source****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, School of Nutrition and Food Science

**Full name of responsible person**

Sanaz Mehrabani

**Position**

MSc student of Nutrition

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Isfahan University Of Medical Sciences

**Full name of responsible person**

Amin Salehi-Abargouei

**Position**

PhD candidate in nutrition

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## **Person responsible for updating data**

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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*