Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 inevention 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 recieve 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

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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

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Position

MSc student of Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

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PhD candidate in nutrition

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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