Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

The effect of skim milk compared to whole milk and apple juice intake at breakfast on appetite and short-term energy intake in obese children

Protocol summary

Summary

The present study will try to examine the effect of skim milk compared to full-fat milk and apple juice on satiety and short-term energy intake. 50 obese children aged 10 to 12 years (25 girls and 25 boy) will be enrolled based on inclusion and exclusion criteria. All the participants will randomly consume the three test beverages (skim milk, whole milk and apple juice) in three intervention periods. Each intervention period will last for two consecutive days. In all intervention days participants will be asked to come to school in a fasted state. They will consume 240 ml of the test beverages with breakfast (energy and the composition of breakfast will be the same for all intervention periods). furthermore, one serving of fruit (similar in 3 intervention periods) will be given to the children as a snack during all intervention days. Intervention periods will be 5 days apart. Visual analog scale (VAS) test for appetite will be filled by participants before and after breakfast, before each snack and lunch to assess the participants' appetite throughout intervention days. furthermore a weighted ad libitum lunch will be provided for all participants to assess the energy intake after each intervention and then the remaining food will be weighted to assess the food intake of children at lunch . The appetite and energy intake of children at lunch on the intervention periods will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072012571N5**
Registration date: **2016-10-09, 1395/07/18**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-10-09, 1395/07/18

Registrant information

Name
Amin Salehi-Abargouei
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Country
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shahid Sadoughi University of Medical Sciences, yazd, Iran

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of skim milk compared to whole milk and apple juice intake at breakfast on appetite and short-term energy intake in obese children

Public title

The effect of skim milk compared to whole milk and apple juice on appetite and energy intake

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Children aged 10-12 years; Children who are defined as obese based on world health organization (WHO) criteria [having a body mass index (BMI) above the 95th percentile based on BMI-for-age charts defined by WHO]; Children and their parents who have intention to be entered to the study; Children who are not on a special diet at the time of the study or do not intend to go on a diet during the study period; Children whose parents do not report any history of cow milk intolerance; Children whose parents do not report any history of congenital or metabolic diseases; Regular breakfast consumption based on information provided by parents. Exclusion criteria: Refusing to participate in at least two intervention periods; Desire to withdraw from the study for any reason.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
Ethics committe of Shahid Sadoughi University of Medical Sciences

Street address
Chancellery for research, Central Building of Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd, Iran

City
Yazd

Postal code
8915173160

Approval date
2016-11-27, 1395/09/07

Ethics committee reference number
IR.SSU.SPH.REC.1394.104

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
Appetite

Timepoint
Before breakfast, after breakfast and 3 times every hour until lunch and Just before lunch

Method of measurement
Visual Analogue Scale (VAS) for appetite

2

Description
Short-term Energy intake

Timepoint
One time at lunch meal

Method of measurement
Analysis of food intake at lunch

Secondary outcomes

1

Description
Weight

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

Method of measurement
measurement Using a digital scale with minimal wear

Intervention groups

1

Description
intervention:Including 240 ml skim milk in breakfast

Category
Other

2

Description
intervention: Including 240 ml apple juice in breakfast

Category
Other

3

Description
intervention: Including 240 ml high fat milk in breakfast
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Two elementary schools in Isfahan (one for girls and one for boys)
Full name of responsible person
Shima Kavezade
Street address
Department of Nutrition, Faculty of Public Health, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, shahid sadughi yazd University of Medical Sciences
Full name of responsible person
Dr. Amirhushang Mehrparvar
Street address
Chancellery for research, Central Building of Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd, Iran
City
Yazd
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, shahid sadughi yazd 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
Nutrition and Food Security Research Center
Full name of responsible person
Dr. Azadeh Najarzadeh
Street address
Nutrition and Food Security Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nutrition and 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
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Position
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Person responsible for scientific inquiries

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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