

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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

Iran (Islamic Republic of)

Phone

+98 35 3820 9100

Email address

abargouei@hlth.mui.ac.ir

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 committee 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 sadoughi 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 sadoughi 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

Nutrition and Food Security Research Center, Shahid
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Full name of responsible person

Shima Kavezade

Position

MSc student of Health Sciences in Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

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Amin Salehi-Abargouei

Position

PhD in Nutrition Sciences

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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

Person responsible for updating data

Contact

Name of organization / entity

Nutrition and Food Security Research Center, Shahid
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Full name of responsible person

Shima Kavezade

Position

MSc student of Health Sciences in Nutrition

Other areas of specialty/work

Street address