

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation effect of daily consumption of whey protein on anthropometric indices , body composition and blood pressure in overweight or obese children

Protocol summary

Study aim

Determining the effect of whey protein on body composition and anthropometric indices and blood pressure in overweight and obese children.

Design

Clinical trials, with parallel groups, one-on-one blind, Block permutation randomized

Settings and conduct

After that the population studied was identified. Demographic data including age and sex, anthropometric information including height and weight, waist circumference and blood pressure, and body composition analysis, before, during and after intervention, will be performed for each interested person. They will also be asked to record their physical activity and diet for 2 days. and each group participates in the study for 8 weeks with iso-calorie diet The participants, the outcome assessor and the data analyst, are unaware of the fact that the individuals received the packages of the intervention or received the placebo. The intervention group and placebo packages have the same size and appearance.

Participants/Inclusion and exclusion criteria

Body mass index percentile higher than 85 Blood pressure less than 160/100 Not suffering from any liver, digestive, kidney, kidney stones, diabetes, thyroid disease Not having allergy to milk and its products Not taking medications that affect body weight

Intervention groups

Individuals are divided into 2 groups according to the randomized block permutation method, and each group participates in the study for 8 weeks with iso-calorie diet. The intervention group consumes a 20 grams whey protein drink once a day, half an hour before eating lunch. The control group also takes 20 grams of maltodextrine once a day, half an hour before lunch.

Main outcome variables

height and weight, waist circumference and blood pressure, and body composition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180825040861N1**

Registration date: **2018-10-09, 1397/07/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-09, 1397/07/17**

Update count: **0**

Registration date

2018-10-09, 1397/07/17

Registrant information

Name

Seyede Zahra Hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3820 6774

Email address

hashemizahra70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-11, 1397/06/20

Expected recruitment end date

2018-10-17, 1397/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation effect of daily consumption of whey protein on anthropometric indices , body composition and blood pressure in overweight or obese children

Public title
Evaluation effect of daily consumption of whey protein on anthropometric indices , body composition and blood pressure in overweight or obese children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Body mass index percentile higher than 85 Blood pressure less than 160/100 being 7-13 years old
Exclusion criteria:
 Suffering from any liver, digestive, kidney, kidney stones, diabetes, thyroid disease Having allergy to milk and its products Taking medications that affect body weight

Age
From **7 years** old to **13 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Block permutation The random assignment method is performed in such a way that it is written in 50 pieces of paper (25 c code and 25 t code) and randomly drawn out of one of the paper in the order that the individuals refer to. It is determined which group to be assigned to.

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants, the outcome assessor and the data analyst, are unaware of the fact that the individuals received the packages of the intervention or received the placebo. The intervention group and placebo packages have the same size and appearance.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

•Ethics committee of Shiraz University of Medical Sciences

Street address

zand street, shiraz University of Medical Sciences

City

shiraz

Province

Fars

Postal code

۷۱۳۳۶ - ۷۱۳۴۸

Approval date

2017-07-23, 1396/05/01

Ethics committee reference number

IR.SUMS.REC.1396.39

Health conditions studied

1

Description of health condition studied

over weight and obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

weight

Timepoint

1.14, 28, 56 th day

Method of measurement

Scales

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" The sachet (once every 2 weeks) will be given to the participants for 8 weeks. Each sachet in the intervention group consists of 20 g of proteins, steviosides and flavors, which should be Consumpted daily half an hour before Lunch up to 8 weeks .(Adding 1 sachet to a 60 ml of boiling water (one quarter of a glass))

Category

Treatment - Other

2

Description

"Control group:" The sachet (once every 2 weeks) will be given to the participants for 8 weeks. Each sachet in the control group consists of 20 g of maltodextrine, steviosides and flavors, which should be Consumed daily half an hour before Lunch up to 8 weeks .(Adding 1 sachet to a 60 ml of boiling water (one quarter of a glass))

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mottahari hospital

Full name of responsible person

Dr Siavash Babajafari

Street address

Rzi bolvard

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Postal code

7153675541

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Email

scnutrition@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Seyed Basir Hashemi

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scnutrition@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

Seyede Zahra Hashemi

Position

Msc Student

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Siavash Babajafari

Position

assistant professor of nutrition

Latest degree

Specialist

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Email

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyedeh Zahra Hashemi

Position

Msc student in Nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Consent form of participation in the project

When the data will become available and for how long

97/6/10

To whom data/document is available

Related parties

Under which criteria data/document could be used

For more information

From where data/document is obtainable

Shiraz university of medical sciences

What processes are involved for a request to access data/document

call or in-person

Comments