

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Aug 2026

Comparison of high-fat and low-carbohydrate weight loss diet with standard weight loss diet on body composition, appetite and anthropometric measurements in overweight and obese children

Protocol summary

Study aim

Comparison and determination the effects of high-fat and low-carbohydrate diet with Standard diet on body composition, appetite, and anthropometric measurements in overweight and obese children

Design

The clinical trial has two intervention groups, parallel groups, single blind and randomized.

Settings and conduct

Demographic questionnaire was used to measure social status, IPAQ-short form (The International Physical Activity Questionnaire) form was used to measure physical activity and The Appetite and Diet Assessment Tool(ADAT) and self-reported score were used to assess appetite. The three-day food record are filled out by the parents or children. Weight measurement is measured with a digital scale with 100 grams accuracy . The individual's height is measured with 0.5 cm accuracy . Waist and hip circumference is measured using a meter. Body composition is assessed with a Body impedance analysis (BIA). Diet sheet with supplementary recommendations to be given to the participant. To measure adherence each week, we will ask the person about their diet performing. Blinding: The evaluator is not aware of the participant's diet. location: Shiraz, Namazi Square, Imam Reza Clinic

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 9-18 years BMI for age above 85th percentile Exclusion criteria: Having a specific diet

Intervention groups

Control group: Low fat and high carbohydrate diet (Standard diet) (25% of total energy as fat, 20% of total energy as protein and 55% of total energy as carbohydrate) Intervention group: High-fat, low-carbohydrate diet (55% of total energy as fat, 20% of total energy as protein , and 25% of total energy as carbohydrate)

Main outcome variables

Height, weight, BMI, waist-to-hip ratio, waist circumference, hip circumference, appetite, adipose tissue, lean tissue, interstitial water

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191121045464N1**

Registration date: **2020-07-06, 1399/04/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-06, 1399/04/16**

Update count: **0**

Registration date

2020-07-06, 1399/04/16

Registrant information

Name

Mohaddeseh Hasanzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3648 0127

Email address

hasanzade-m@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-05, 1399/04/15

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of high-fat and low-carbohydrate weight loss diet with standard weight loss diet on body composition, appetite and anthropometric measurements in overweight and obese children

Public title
Comparison of the effects of two weight loss diets (High fat diet and Standard diet)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 BMI(Body mass index) for age above 85th percentile
 Parents' consent to participate in the project
Exclusion criteria:
 BMI (body mass index) for age is normal

Age
From **9 years** old to **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals using the Permuted Block Randomization method will be divided into two groups. To create a random sequence in the block randomization approach, the website <http://www.sealedenvelopepe.com> will be used. The project methodologist is also given a random sequence to hide the allocation concealment. Then, the researcher communicates with the mentioned people based on the order of the participants entering the study and communicates with the said person about the random allocation of the participants to the study and asks about the random allocation of the participant to the specific group. For each intervention, a number (multi-digit code) is defined and entered on the envelope according to the random sequence created.

Blinding (investigator's opinion)
Single blinded

Blinding description
The trial is planned in such a way that the evaluator of weight and body composition does not understand which of the two groups (High-fat weight loss diet and Standard weight loss diet) belong to the participant.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences Central Building, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-12-12, 1398/09/21

Ethics committee reference number

IR.TUMS.VCR.REC.1398.694

Health conditions studied

1

Description of health condition studied

Overweight and obesity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Children's body mass index percentile

Timepoint

The first week and the sixth week

Method of measurement

Body weight in kilogram divided by the square of the height in meters

2

Description

Individual weight with minimum clothing and no shoes with 0.1 kg accuracy

Timepoint

The first week and the sixth week

Method of measurement

Scale

3

Description

Children's height in standing position without shoes with 0.5 accuracy
Timepoint
The first week and the sixth week
Method of measurement
Stadiometer

4

Description
Waist circumference measurement in the midline between the lower rib and the upper part of the iliac bone
Timepoint
The first week and the sixth week
Method of measurement
Meter

5

Description
Measuring the most articulated part of the hip
Timepoint
The first week and the sixth week
Method of measurement
Meter

6

Description
Waist to hip ratio
Timepoint
The first week and the sixth week
Method of measurement
Waist circumference divided by hip circumference

7

Description
Appetite score by ADAT questionnaire(The Appetite and Diet Assessment Tool)
Timepoint
The first week and the sixth week
Method of measurement
ADAT questionnaire(The Appetite and Diet Assessment Tool)

8

Description
Fat mass measured by Bioelectrical Impedance Analysis (BIA)with minimal clothing and no shoes
Timepoint
The first week and the sixth week
Method of measurement
Bioelectrical Impedance Analysis

9

Description
Lean body mass measured by Bioelectrical Impedance Analysis with minimal clothing and no shoes
Timepoint

The first week and the sixth week
Method of measurement
Bioelectrical Impedance Analysis (body weight - fat mass)

10

Description
Interstitial water measured by Bioelectrical Impedance Analysis with minimal clothing and no shoes
Timepoint
The first week and the sixth week
Method of measurement
Bioelectrical Impedance Analysis

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: High fat and low carbohydrate (55% of total energy as fat, 20% of total energy as protein 25% of total energy as carbohydrate) and the amount of diet energy is 500 kcal below the individual requirement .Everyone will also be given dietary advice.The duration of the diet will be 6 weeks
Category
Treatment - Other

2

Description
Control group: Standard diet (55% of total energy as carbohydrate, 20% of total energy as protein 25% of total energy as fat) and the amount of diet energy is 500 kcal below the individual requirement .Everyone will also be given dietary advice.The duration of the diet will be 6 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
کلینیک زیبا آفرین
Full name of responsible person
محدثه حسن زاده
Street address
4th floor,Kasra Building,Ordibehesht Ave,Mulla Sadra Street
City
Shiraz
Province
Fars
Postal code

7134684499

Phone

+98 71 3648 0127

Email

mahdishealth@outlook.com

Web page address

http://mahdishealth.com/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Mahmoodi

Street address

6th Floor, School of Nutrition and Dietetics, Hojjat
Doust Alley, Naderi St, Keshavarz Blvd.

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1416643931

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+98 21 8895 5805

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m-mahmoudi@sina.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohaddeseh Hasanzadeh

Position

Student of Master of science

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohaddeseh Hasanzadeh

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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