

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The impact of Dietary Approach to Stop Hypertension eating plan on fasting blood glucose and lipid profiles in children with metabolic syndrome: A cross-over study

Protocol summary

Summary

The objective: Evaluation the impact of a DASH diet on components of metabolic syndrome in children. Design: cross-over trial. Participants: matured female aged 13-18 y with metabolic syndrome based on ATPIII definition that have no cardio-vascular; gastrointestinal, renal and liver disorders diseases or medication/supplement use. Exclusion criteria: incidence of gastrointestinal, renal and liver disorders; lack of adherence to the prescribed diets. Setting and conduct: Participants will be randomly assigned to take DASH diet or usual recommendations after a 2 wk run-in period. The participants will be randomly assigned to receive either a DASH diet or usual dietary recommendations, each for 6 week, followed by a 4-week washout period. Then the participants will move to the alternate arm. Appropriate statistical methods will be applied for data analyses. Interventions: DASH diet and usual dietary recommendations. Main outcomes: Anthropometric measures, blood pressure, biochemical measures including fasting plasma glucose, serum insulin, triglyceride, total-cholesterol, high density lipoprotein cholesterol (HDL-c)-, and low density lipoprotein cholesterol (LDL-c) will be measured at baseline and at the end of each intervention phase.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110191485N6**
Registration date: **2012-02-01, 1390/11/12**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-02-01, 1390/11/12

Registrant information

Name

Ahmad Esmailzadeh

Name of organization / entity

Department of Nutrition, School of Public Health,
Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2791

Email address

esmailzadeh@hlth.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of
Medical Sciences

Expected recruitment start date

2011-10-19, 1390/07/27

Expected recruitment end date

2011-12-29, 1390/10/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of Dietary Approach to Stop Hypertension eating plan on fasting blood glucose and lipid profiles in children with metabolic syndrome: A cross-over study

Public title

The impact of Dietary Approach to Stop Hypertension eating plan on features of metabolic syndrome in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: female; aged 13-18 y; having metabolic syndrome according to modified Adult Treatment Panel III definition; being mature, lack of gastrointestinal, renal, liver and thyroid disorders; lack of diabetes, rheumatoid arthritis, Lupus; sever infection and trauma; surgery and allergy; lack of adherence to a specific diet and the use of medications such as multivitamin supplementation, appetite suppressive, omega-3 fatty acids, Aspirin, NSAIDs, etc in the past 6 months, lack of hormone therapy. Exclusion criteria: incidence of gastrointestinal, renal, liver and thyroid disorders ; diabetes, rheumatoid arthritis, Lupus, sever infection; trauma; surgery; allergy; alterations in physical activity and supplement use; lack of adherence to the prescribed diets

Age

From **13 years** old to **18 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **45**

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

Ethical Committee of Isfahan University of Medical Sciences

Street address

Isfahan university of medical sciences, Hezar Jerib Ave

City

Isfahan

Postal code

Approval date

2011-09-03, 1390/06/12

Ethics committee reference number

390245

Health conditions studied

1

Description of health condition studied

Metabolic syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

In the beginning and at the end of each intervention phase

Method of measurement

Colorimetric by using glucose oxidize

2

Description

Systolic blood pressure

Timepoint

In the beginning and at the end of each intervention phase

Method of measurement

digital sphygmomanometer

3

Description

HDL-C

Timepoint

In the beginning and at the end of each intervention phase

Method of measurement

Commercial kits

4

Description

Total cholesterol

Timepoint

In the beginning and at the end of each intervention phase

Method of measurement

Commercial kits

5

Description

Triglyceride serum

Timepoint

In the beginning and at the end of each intervention phase

Method of measurement

Commercial kits

6

Description

Diastolic blood pressure

Timepoint

In the beginning and at the end of each intervention phase

Method of measurement

digital sphygmomanometer

Secondary outcomes

1

Description

Waist circumference

Timepoint

In the beginning and at the end of each intervention phase

Method of measurement

meter

2

Description

weight

Timepoint

In the beginning and at the end of each intervention phase

Method of measurement

Digital scale

Intervention groups

1

Description

DASH diet: 53-58% of calorie from carbohydrate, 15-18% from proteins, and 26-30% from fats. These patients will also be advised to increase their intakes of fruits and vegetables, low dairy products, whole grains and decrease their saturated fatty acids, total cholesterol, total fat, red meat and sweets intake.

Category

Treatment - Other

2

Description

Diet including usual dietary recommendations: information about healthy diet has been prescribed for this group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Food security and research center

Full name of responsible person

Management of the center, Dr Leila Azadbakht

Street address

School of Nutrition and Food Science, Isfahan university of medical sciences, Hezar Jerib Ave,

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. Adibi

Street address

Isfahan university of medical sciences, Hezar Jerib Ave

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

100

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

Department of Community Nutrition, School of Nutrition and Food Science, Isfahan University of Medic

Full name of responsible person

Dr Ahmad Esmailzadeh

Position

Associate Professor

Other areas of specialty/work

Street address

Isfahan university of medical sciences, Hezar Jerib Ave

City

Isfahan

Postal code

Phone

+98 31 1792 2720

Fax

Email

Esmailzadeh@hlth.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Food Security Research Center, Isfahan University of Medical sciences

Full name of responsible person

Dr Ahmad Esmailzadeh

Position

Associate Professor

Other areas of specialty/work

Street address

Isfahan university of medical sciences, Hezar Jerib Ave

City

Isfahan

Postal code

Phone

+98 31 1792 2720

Fax

Email

Esmailzadeh@hlth.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Community Nutrition, School of

Nutrition and Food Science, , Food security and research

Full name of responsible person

Dr Ahmad Esmailzadeh

Position

Associate Professor

Other areas of specialty/work

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City

Isfahan

Postal code

Phone

Fax

Email

Esmailzadeh@hlth.mui.ac.ir

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