

# 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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Isfahan university of medical sciences, Hezar Jerib Ave

**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*