

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The Effect of DASH (Dietary Approach to Stop Hypertension) on IRS1 and PPARY2 Genes Expression in Obese Women

Protocol summary

Summary

We aimed a randomized controlled clinical trial to determine the effects of Dietary Approaches to Stop Hypertension (DASH) diet on IRS and PPAR- γ gene expression in 60 healthy obese women who would be referred from health centers. Subject would not be have history of diabetes, heart failure, renal failure, hyperlipidemia, hormonal disease and supplement or drug consumption or weight loss more than 10% in six months earlier. They would be excluded if their weight would reduce more than 5% or they wouldn't have adherence or incidence of disease. After 2 week run in participants would be randomly assigned to a control diet with healthy advices or the DASH eating pattern, each for 12 weeks . Finally IRS and PPAR- γ gene expression would be measured by real time PCR in blood monocyte and that would be compared between two groups by SPSS statistical software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090719072N1**

Registration date: **2015-02-11, 1393/11/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-11, 1393/11/22

Registrant information

Name

Marzieh Kafeshani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2013-03-31, 1392/01/11

Expected recruitment end date

2015-06-30, 1394/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of DASH (Dietary Approach to Stop Hypertension) on IRS1 and PPARY2 Genes Expression in Obese Women

Public title

The Effect of Dietary Approach to Stop Hypertension (DASH) on Insulin Resistance

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion Criteria: female; Body Mass Index above 30; age 20-50; absence of cardiovascular; hepatic; renal; thyroid; diabetes; rheumatoid arthritis; lupus; severe infection; trauma; allergy disease; don't use of multivitamin and mineral or omega-3 fatty acids supplements; don't regular use of antacid drugs containing magnesium and calcium ; consumption Aspirin and Non Steroid Anti Inflammation; and anti-depressant and hormone drugs; lack of pregnancy and

breastfeeding; don't get weight loss in 6 months (more than 1 kg; don't use of tobacco and alcohol. Exclusion criteria: Failure to follow the prescribed diet(energy intake is different more than 300 calorie from prescribed as regard to food record analysis), if weight change is more than 5%, diagnosis one of mentioned disease in inclusion criteria and using of chemical or herbal medicines during the study.

Age

From **20 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University OF Medical Science

Street address

Nutrition School, Isfahan University of Medical Science, Hezarjerib Street, Azadi Squire, Isfahan.

City

Isfahan

Postal code**Approval date**

2013-07-06, 1392/04/15

Ethics committee reference number

392330

Health conditions studied**1****Description of health condition studied**

healthy obese volunteer

ICD-10 code

E66.9

ICD-10 code description

Simple obesity NOS

Primary outcomes**1****Description**

PPAR gamma Gene Expression

Timepoint

Before Intervention and After 3 Months

Method of measurement

Real Time Polymerase Chain Reaction

2**Description**

IRS1 Gene Expression

Timepoint

Before Intervention and After 3 Months

Method of measurement

Real Time Polymerase Chain Reaction

3**Description**

insulin resistance

Timepoint

Before Intervention and After 3 Months

Method of measurement

Hemostatic Model Assessment(HOMA)

Secondary outcomes**1****Description**

Weight

Timepoint

Before Study and After 3 Months

Method of measurement

Scale

2**Description**

Fasting Sugar

Timepoint

Before Study and After 3 Months

Method of measurement

Caloremetric

3**Description**

Fasting Insulin

Timepoint

Before Study and After 3 Month

Method of measurement

Elisa Method

Intervention groups

1

Description

The intervention group will prescribe DASH diet that is rich in fruits, vegetables, whole grains, and low fat dairy products, and low in saturated fat, total fat, cholesterol, refined grains and sweets. The diets would be prescribed weekly, and an exchange list would be given to each patient for exchanging food items and counting the calories. A nutritionist will teach subjects how to apply the exchange list and write food diaries. Every participant will bring her 3-day diet records every month, and the dairies would be reviewed by N4 nutritional software and their compliance would be assessed by analyzing the three food record diaries monthly and the attendance at meetings and monthly visits.

Category

Lifestyle

2

Description

The control group was recommended to "eat as usual" and received healthy dietary advises which would be printed on a paper. Every participant will bring his 3-day diet records every month, and the dairies would be reviewed by NUTRITIONIST 4 software and their diet was assessed by analyzing the three food record diaries.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Food Security Reserch Center

Full name of responsible person

Dr Mohammad Hasan Entezari

Street address

Nutrition School, Isfahan University of Medical Science, Hezarjerib Street, Azadi Squire, Isfahan,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medica Science ,Deputy Director of Research and Development

Full name of responsible person

Dr Payman Adibi

Street address

Deputy Director of Research and Development, Isfahan University of Medical Science, Hezarjerib Street, Azadi Squire, Isfahan, ,

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medica Science ,Deputy Director of Research and Development

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

Isfahan University of Medical Science

Full name of responsible person

Dr Mohammad Hasan Entezari

Position

Assitanat Professor

Other areas of specialty/work

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Person responsible for updating data

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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