

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Evaluation of sesame (*Sesamum indicum*) effects on some biochemical parameters in type 2 diabetic patients

#### Protocol summary

##### Summary

This study was aimed to assess effect of sesame on lipid profile, blood pressure, oxidative stress and inflammatory markers. A total of 50 patients with type 2 diabetes will be recruited. Inclusion criteria are: subjects between 18-60 years old; type 2 diabetic patients without insulin therapy; patients with history of diabetes more than one year; patients with body mass index between 18 to 35 kg/m<sup>2</sup>. Exclusion criteria are: pregnant or lactating women; smokers and alcohol consumers; patients consume antioxidant supplements (vitamin E and C, carotenoids and coQ10); patients with cardiac, hepatic, respiratory and chronic renal diseases; patients with acute or chronic inflammation. Subjects will be randomly assigned into groups 1) sesame (intervention) and 2) usual breakfast (control) and will be followed up for 6 weeks. Lipid profile, blood pressure, oxidative stress and inflammatory markers will be measured at baseline and 6 weeks after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201105161640N4**  
Registration date: **2011-11-27, 1390/09/06**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-11-27, 1390/09/06

##### Registrant information

##### Name

Parvin Mirmiran

##### Name of organization / entity

Obesity Research Center, Research Institute for

Endocrine Sciences, Shahid Beheshti University of Me

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2243 2500

##### Email address

mirmiran@endocrine.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Obesity Research Center, Research Institute for Endocrine Science, Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2011-05-22, 1390/03/01

##### Expected recruitment end date

2011-07-23, 1390/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of sesame (*Sesamum indicum*) effects on some biochemical parameters in type 2 diabetic patients

##### Public title

Evaluation of sesame (*Sesamum indicum*) effects on some biochemical parameters in type 2 diabetic patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: subjects between 18-60 years old; type 2 diabetic patients without insulin therapy; patients with history of diabetes more than one year; patients with body mass index between 18 to 35 kg/m<sup>2</sup>. Exclusion criteria: pregnant or lactating women; smokers and alcohol consumers; patients consume antioxidant

supplements (vitamin E and C, carotenoids and coQ10); patients with cardiac, hepatic, respiratory and chronic renal diseases; patients with acute or chronic inflammation

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **50**

#### 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

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

##### Street address

No 24, Parvaneh st., Yemen Blvd., Chamran exp.

##### City

Tehran

##### Postal code

#### Approval date

2011-08-02, 1390/05/11

#### Ethics committee reference number

349EC

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 diabetes

#### ICD-10 code

E11

#### ICD-10 code description

Non-insulin-dependent diabetes mellitus

## Primary outcomes

### 1

#### Description

Lipid profile

#### Timepoint

Baseline and 6 weeks after intervention

#### Method of measurement

Biochemistry analysis

### 2

#### Description

Blood pressure

#### Timepoint

Baseline and 6 weeks after intervention

#### Method of measurement

Monometer

### 3

#### Description

Oxidative stress

#### Timepoint

Baseline and 6 weeks after intervention

#### Method of measurement

Biochemical analysis

### 4

#### Description

Inflammatory markers

#### Timepoint

Baseline and 6 weeks after intervention

#### Method of measurement

Biochemical analysis

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Tahini (sesame)- 2 table spoon with bread in breakfast for 6 weeks

#### Category

Treatment - Other

### 2

#### Description

2 slices bread with cheese in breakfast for 6 weeks

#### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Diabetes clinice of Talaghani Hospital

**Full name of responsible person****Street address****City**

Tehran

## 2

### Recruitment center

**Name of recruitment center**

Iran Diabetes Association

**Full name of responsible person****Street address****City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Research Institute for Endocrine Science, Shaheed Beheshti University of Medical Sciences

**Full name of responsible person**

parvin mirmiran

**Street address**

No.24, Parvaneh St, Yemen Blvd, Chamran highway

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Institute for Endocrine Science, Shaheed Beheshti 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**

Obesity Research Center, Research Institute for Endocrine Science, Shaheed Beheshti University of Med

**Full name of responsible person**

Parvin Mirmiran

**Position**

Director of Nutrition Unit of Obesity Research Center/  
PhD in Nutrition

**Other areas of specialty/work****Street address**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Obesity Research Center, Research Institute for Endocrine Science, Shahid Beheshti University of Med

**Full name of responsible person**

Zahra Bahadoran

**Position**

MSc in Nutrition

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**Postal code****Phone****Fax****Email****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*