

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/m². 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/m². 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

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

City

Tehran

Postal code

Phone

+98 21 2243 2500

Fax

Email

mirmiran@endocrine.ac.ir

Web page address

Person responsible for scientific 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

PhD in Nutrition

Other areas of specialty/work

Street address

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

City

Tehran

Postal code

Phone

+98 21 2243 2500

Fax

Email

mirmiran@endocrine.ac.ir

Web page address

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

Other areas of specialty/work

Street address

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

City

Tehran

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