

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Effect of sesamin supplementation on the glycemic indices, lipid profile, serum levels of inflammatory markers, malondialdehyde and adiponectin in type2 diabetic patients.

Protocol summary

Summary

Objectives: The purpose of this study is investigating the effect of sesamin supplementation on some lipid profile, glycemic indices and serum levels of inflammatory markers, malondialdehyde and adiponectin in type 2 diabetic patients. Design: 44 patients with type 2 diabetes from both of sex and aged between 30-60 years old are randomly assigned to two intervention and control groups. Setting and conduct : The subjects in the intervention and control groups will receive 200 mg sesamin and 200 mg starch capsule daily for 8 weeks, respectively. Participants including major eligibility criteria: Main inclusion criteria: having type 2 diabetes; 30 to 60 years old; BMI<30; Not having severe cardiovascular, hepatic, kidney, gastrointestinal, thyroid or inflammatory diseases; Not using insulin or taking corticosteroids, NSAIDS, immunosuppressives, multivitamin-mineral, fiber and omega 3 supplements since 3 weeks prior to the study and during intervention period; No smoking or addiction; No pregnancy or lactation; Not having any weight loose or weight gain regimes; No use of antibiotics. Main exclusion criteria: drug type and dose fluctuation during intervention period; unwilling to continue the study; looking sensitivity or allergy. Intervention: The subjects in the intervention and control groups will receive 200 mg sesamin and 200 mg starch capsule daily for 8 weeks, respectively. Subjects will ask not to change their diet, medications and physical activity routine throughout the trial. main outcome measures (variables): serum levels of glucose, IL-6, TNF- α , hs-CRP, HbA1c, lipid profile, adiponectin and malondialdehyde are evaluated at the beginning and end of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061818134N1**

Registration date: **2014-11-23, 1393/09/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-23, 1393/09/02

Registrant information

Name

Mehrnoush Zakerzadeh

Name of organization / entity

Ahvaz Jundishapur University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 7079

Email address

zakerzadeh.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of sesamin supplementation on the glycemic indices, lipid profile, serum levels of inflammatory markers, malondialdehyde and adiponectin in type2 diabetic patients.

Public title

Effect of sesamin supplementation in diabetic patient

Purpose

Treatment

Inclusion/Exclusion criteria

Main inclusion criteria: : having type 2 diabetes; 30 to 60 years old; BMI<30; Not having severe cardiovascular, hepatic, kidney, gastrointestinal, thyroid or inflammatory diseases; Not using insulin or taking corticosteroids, NSAIDS, immunosuppressives, multivitamin-mineral, fiber and omega 3 supplements since 3 weeks prior to the study and during intervention period; No smoking or addiction; No pregnancy or lactation; Not having any weight loose or weight gain regimes; No use of antibiotics. Main exclusion criteria: drug type and dose fluctuation during intervention period; unwilling to continue the study; looking sensitivity or allergy.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Ahvaz Jundishapur University of medical sciences

Street address

Ahvaz Jundishapur University of Medical Science
Ahvaz, Golestan Ave.

City

Ahvaz

Postal code**Approval date**

2013-12-21, 1392/09/30

Ethics committee reference number

ajums.REC.1392.213

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**

Fasting Blood Sugar

Timepoint

Before and after 8 weeks

Method of measurement

spectrophotometry

2**Description**

Hemoglobin A1c

Timepoint

Before and after 8 weeks

Method of measurement

Chromatography

3**Description**

Total Cholesterol

Timepoint

Before and after 8 weeks

Method of measurement

spectrophotometry

4**Description**

Triglyceride

Timepoint

Before and after 8 weeks

Method of measurement

spectrophotometry

5**Description**

HDL.c

Timepoint

Before and after 8 weeks

Method of measurement

spectrophotometry

6

Description

LDL.c

Timepoint

Before and after 8 weeks

Method of measurement

spectrophotometry

7

Description

hs-CRP

Timepoint

Before and after 8 weeks

Method of measurement

ELISA

8

Description

TNF-α

Timepoint

Before and after 8 weeks

Method of measurement

ELISA

9

Description

IL-6

Timepoint

Before and after 8 weeks

Method of measurement

ELISA

10

Description

adiponectin

Timepoint

Before and after 8 weeks

Method of measurement

ELISA

11

Description

malondialdehyde

Timepoint

Before and after 8 weeks

Method of measurement

TBARS

12

Description

Dietary Factors

Timepoint

Before and after 8 weeks

Method of measurement

24h recall

13

Description

Insulin

Timepoint

Before and after 8 weeks

Method of measurement

ELISA

14

Description

Blood Pressure

Timepoint

before and after intervention

Method of measurement

Medical mercury sphygmomanometer

Secondary outcomes

1

Description

body weight

Timepoint

Before and after 8 weeks

Method of measurement

scale

2

Description

Waist circumference

Timepoint

Before and after 8 weeks

Method of measurement

meter

3

Description

hip circumference

Timepoint

Before and after 8 weeks

Method of measurement

meter

4

Description

body adiposity index

Timepoint

Before and after 8 weeks

Method of measurement

Hip circumference (cm)/height (m)^{1.5} - 18

5

Description

body fat%

Timepoint

Before and after 8 weeks

Method of measurement

omron

Intervention groups

1

Description

Intervention group: Sesamine supplement, 200 mg caps per day for 8 weeks

Category

Treatment - Drugs

2

Description

Placebo group: placebo caps for 6 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital Diabetes Clinic

Full name of responsible person

Mehrnoush Zakerzadeh

Street address

Ahvaz Jondishapur University Of Medical Sciences,
Golestan Ave. Ahvaz.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Dr. Nader Saki

Street address

Ahvaz Jundishapur University of Medical Science,
Golestan Ave. Ahvaz.

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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

Vice chancellor for research, Ahvaz Jundishapur
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

School of Paramedicine, Ahvaz Jondishapur University
Of Medical Sciences

Full name of responsible person

Mehrnoush Zakerzadeh

Position

Msc. in Nutrition sciences

Other areas of specialty/work

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Position

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Other areas of specialty/work

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00

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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