Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)
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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
Befor 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
Befor and after 8 weeks
Method of measurement
spectrophotometry

4

Description
Triglyceride
Timepoint
Befor and after 8 weeks
Method of measurement
spectrophotometry

5

Description
HDL.c
Timepoint
Befor and after 8 weeks
Method of measurement

spectrophotometry

6

Description
LDL.c
Timepoint
Befor and after 8 weeks
Method of measurement
spectrophotometry

7

Description
hs-CRP
Timepoint
Befor and after 8 weeks
Method of measurement
ELISA

8

Description
TNF-a
Timepoint
Befor and after 8 weeks
Method of measurement
ELISA

9

Description
IL-6
Timepoint
Befor and after 8 weeks
Method of measurement
ELISA

10

Description
adiponectin
Timepoint
Befor and after 8 weeks
Method of measurement
ELISA

11

Description
malondialdehyde
Timepoint
Befor and after 8 weeks
Method of measurement
TBARS

12

Description
Dietary Factors
Timepoint
Befor and after 8 weeks
Method of measurement
24h recall

13

Description
Insulin
Timepoint
Befor 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.
City
Ahvaz
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
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Person responsible for updating data

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Name of organization / entity
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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City

Ahvaz

Postal code

Phone

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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