

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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- $\alpha$ , 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 glyemic 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- $\alpha$

### **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)<sup>1.5</sup> - 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

##### Position

Msc. in Nutrition sciences

##### Other areas of specialty/work

##### Street address

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Golestan Ave. Ahvaz

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##### Email

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mehr.zakerzadeh@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz Jundishapur University of medical sciences

##### Full name of responsible person

Dr. Majid Mohamadshahi

##### Position

Ph.D Associated Professor

##### Other areas of specialty/work

##### Street address

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##### Web page address

## Person responsible for updating data

#### Contact

##### 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**

**Street address**

Ahvaz Jondishapur University of Medical Sciences,  
Golestan Ave. Ahvaz

**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*