

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Effect of sesame seeds on Fasting Blood Sugar, HbA1C, liver enzymes, cholesterol and triglycerides in patients with type 2 diabetes: A randomized clinical trial

Protocol summary

Study aim

Effect of sesame seeds on Fasting Blood Sugar, HbA1C, liver enzymes, cholesterol and triglycerides in patients with type 2 diabetes

Design

According to the arrival of the subjects in the laboratory, 60 g per day sesame seeds were given to the patients in the case group at 30 g for 2 servings for 2 months and not given to the sesame control group.

Settings and conduct

This research is a randomized clinical trial. The study population included patients with type 2 diabetes who referred to the specialized laboratory of medical school of Rafsanjan University of Medical Sciences in 2015.

Participants/Inclusion and exclusion criteria

Entry requirements: Type 2 diabetes, aged 65-40 years, fasting blood glucose greater than 12 mg / dl and less than 250 mg / dl, serum cholesterol 250-210 mg / dl, triglyceride 200-200 mg / dl, non-intake Blood lipid lowering drugs use glucose lowering drugs such as metformin and glibenclamide when taking glucose lowering drugs. Exit conditions: insulin infusion, history of cardiovascular, liver, kidney, hypothyroidism or hyperthyroidism, high blood pressure, history of insulin treatment, oil or sesame consumption, changes in daily physical activity and diet, pregnancy and lactation, use Oral contraceptives include alcohol, cigarette and drug use history.

Intervention groups

Sesame seeds were prepared in 30g packages. Sesame Consumption: Patients in the case group received 60 grams of sesame seeds per day at 30 grams for 2 months and were not given to the control group. Regarding the fact that the life of the red blood cell is 4 months, the average amount of glycosylated hemoglobin was considered to be 2 months.

Main outcome variables

In general, the benefits of using sesame seeds to reduce the side effects of type 2 diabetes are the aim of this study is to evaluate the effect of sesame seeds on some of the biochemical factors in patients with type 2 diabetes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190114042359N1**

Registration date: **2019-02-27, 1397/12/08**

Registration timing: **retrospective**

Last update: **2019-02-27, 1397/12/08**

Update count: **0**

Registration date

2019-02-27, 1397/12/08

Registrant information

Name

Atena-Sadat Ghoreishi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4331 5306

Email address

atooo4929@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-05-05, 1394/02/15

Expected recruitment end date

2015-08-11, 1394/05/20

Actual recruitment start date

2015-05-05, 1394/02/15

Actual recruitment end date

2015-08-11, 1394/05/20

Trial completion date

2015-09-16, 1394/06/25

Scientific title

Effect of sesame seeds on Fasting Blood Sugar, HbA1C, liver enzymes, cholesterol and triglycerides in patients with type 2 diabetes: A randomized clinical trial

Public title

Effect of sesame seeds on patients with type 2 diabetes

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Included type 2 diabetes Age 40,65 years Fasting Blood Glucose greater than 12 mg,dl and less than 250 mg,dl Serum cholesterol 210,250 mg,dl Triglyceride 200 mg,dl Non use of lipid lowering drugs Using glucose lowering drugs: metformin and glibenclamide

Exclusion criteria:

Insulin infusion History of cardiovascular, liver, kidney, hypothyroidism or hyperthyroidism High blood pressure History of insulin therapy Oil consumption or sesame seeds Changes in daily physical activity and diet during the course of study Pregnancy and lactation Use of oral contraceptives History of alcohol use, smoking and narcotics

AgeFrom **40 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60**Actual sample size reached: **72****Randomization (investigator's opinion)**

Randomized

Randomization description

The selected individuals are randomly assigned a random numbered table, in which the subjects are divided into two equal groups of 36 (case and control).

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

College of Medical Sciences, University of Medical Sciences, Pistachio Blvd, Gulf Blvd, Rafsanjan.

City

Rafsanjan

Province

Kerman

Postal code

7718175911

Approval date

2015-03-04, 1393/12/13

Ethics committee reference number

31/3757

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

Fasting Blood Sugar, HbA1c,cholesterol,triglycerides,Alanine Transaminase, Alkaline Phosphatase

Timepoint

At the beginning of the study (before the intervention) and 2 months after the start of consumption of sesame seeds

Method of measurement

Pathological tests performed on blood samples

Secondary outcomes**1****Description**

Fasting Blood Sugar, HbA1C, cholesterol, triglycerides, Alanine Transaminase, Alkaline Phosphatase

Timepoint

At the beginning of the study (before the intervention) and 2 months after the start of consumption of sesame seeds

Method of measurement

Pathological tests performed on blood samples

Intervention groups

1

Description

582/5000 Randomly selected. Sesame seeds are purchased from agricultural areas of Yazd and, after confirmation of their species, are put up by botanical experts in packages of 30 grams. In the case group, 60 grams per day of sesame seeds are given in two meals (morning and evening) of 30 grams for 2 months. To weigh 60 g of sesame seeds daily, use two plastic containers in a package and add 30 g of sesame seeds to each of them. In the case group, we will be training daily 2 packets of sesame seeds at 2 o'clock and at the specified hour. After 2 months, all pathological tests are performed again for comparison with the control group.

Category

Treatment - Drugs

2

Description

Control group: They are randomly selected and do not consume any sesame seeds. After 2 months, all pathological tests are performed again for comparison with the intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Laboratory of Rafsanjan college of Medical School

Full name of responsible person

Dr Mahdi Mahmoudi

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College of Medical Sciences, University of Medical Sciences, Pistachio Blvd, Gulf Blvd, Rafsanjan.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr Mahdi Mahmoudi

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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

Rafsanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Atena Sadat Ghoreishi

Position

Faculty of Para-medicine

Latest degree

Master

Other areas of specialty/work

Biochemistry

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Jiroft University of Medical Sciences, Shahed Square, Jiroft.

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

There is a possibility to share some of the data

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Data will be available to researchers working in academic and academic institutions.

Under which criteria data/document could be used

The data of the questionnaires were analyzed by SPSS software version 0.21. Quantitative data are reported as " $\pm$ standard deviation" and qualitative data are reported as "number (percent)". In order to compare the mean biochemical changes in the case and control groups, the Independent two-sample t-test will be used.

From where data/document is obtainable

Send the following message to the following email:
atooo4929@yahoo.com

What processes are involved for a request to access data/document

From the time the email is sent, requesting information until the request is answered is less than 1 week.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Jeeroft University of Medical Sciences

Full name of responsible person

Atena sadat Ghoreishi

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Latest degree

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