

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Investigation the effect of Nigella Sativa oil on Glucose and Lipid Profile control in Patients with Type 2 Diabetes.

Protocol summary

Summary

A randomized double-blind clinical trial is conducted on 72 type 2 diabetic men and women (36 people in each group) for 3 months. Among diabetes patients who come to diabetes center, subjects who have 30-60 years old and receive regular type 2 diabetes drugs was chosen. Patients who receive insulin, Cardiovascular, renal, liver, thyroid disorders, patients who receive anti coagulant (aspirin, vitamin E, and other herbal) drugs and pregnant and lactation women were excluded after matching subjects for age, sex and duration of diabetes. Subjects divided into intervention and placebo group randomly. Intervention group receive 3 black seed capsules that contain 1000 mg black seed extract, and placebo group receive three 1000 mg sunflower oil capsules before each meals for 3 months. In beginning and end of the 3 months, a blood sample was collected from subjects after 12-14 hours fasting and biochemical analyses were conducted that include: fasting blood sugar(FBS), Glycated hemoglobin(hba1c), total cholesterol(TC), High density lipoprotein(HDL), triglyceride(TG) and Low density lipoprotein(LDL) is calculated by friedwald equation. Anthropometric measurements, systolic and diastolic blood pressure, 24hr diet recall and physical activity also measures in beginning and end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013090814588N1**
Registration date: **2014-04-29, 1393/02/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-29, 1393/02/09

Registrant information

Name

Javad Heshmati

Name of organization / entity

Kermanshah university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 8423 1045

Email address

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences, Vice -
Chancellery of Research & Technology Affairs

Expected recruitment start date

2014-04-09, 1393/01/20

Expected recruitment end date

2014-10-12, 1393/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of Nigella Sativa oil on Glucose and Lipid Profile control in Patients with Type 2 Diabetes.

Public title

Effects of Nigella Sativa oil supplementation on Glucose and Lipid Profile Indices in Patients with Type 2 Diabetes.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1-type 2 diabetes patients, 2-taking routine diabetes drugs Exclusion Criteria: 1- taking insulin patients, 2- Cardiovascular, Renal, thyroid

dysfunctions and liver diseases patients, 3-patients who taking anti coagulant drugs like Aspirin, Vitamin E and other Herbal drugs, 4-pregnant and lactating women.

Age

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

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **72**

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

Kermanshah University of Medical Sciences

Street address

Number 2 Building, Kermanshah university of medical science, Shahid beheshti Avenue, Kermanshah, Iran

City

Kermanshah

Postal code

Approval date

2013-07-31, 1392/05/09

Ethics committee reference number

17988

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(FBS)

Timepoint

beginning and end of the study

Method of measurement

blood sample

2

Description

glycated hemoglobin(hba1c)

Timepoint

beginning and end of the study

Method of measurement

blood sample

3

Description

total cholestrol(TC)

Timepoint

beginning and end of the study

Method of measurement

blood sample

4

Description

High density lipoprotein (HDL)

Timepoint

beginning and end of the study

Method of measurement

blood sample

5

Description

triglyceride (TG)

Timepoint

beginning and end of the study

Method of measurement

blood sample

6

Description

Low density lipoproteins (LDL)

Timepoint

beginning and end of the study

Method of measurement

blood sample

Secondary outcomes

1

Description

Height

Timepoint

beginning and end of the study

Method of measurement

Height Gauges

2

Description

Weight

Timepoint

beginning and end of the study

Method of measurement

Scale

3

Description

Waist Circumference

Timepoint

beginning and end of the study

Method of measurement

tape

4

Description

Hip Circumference

Timepoint

beginning and end of the study

Method of measurement

tape

5

Description

Blood pressure

Timepoint

beginning and end of the study

Method of measurement

pressure meter

6

Description

Diet

Timepoint

beginning and end of the study

Method of measurement

24 hour food recall

7

Description

Physical Activity

Timepoint

beginning and end of the study

Method of measurement

physical activity questionnaire

Intervention groups

1

Description

Intervention group: Consumption of 3 gr/day Nigella Sativa oil provided by Barij pharmaceutical company(1 gr

soft gel capsule 3 times a day) for 3 months

Category

Treatment - Drugs

2

Description

Control group: 3 gr/day sunflower oil provided by Barij pharmaceutical company(1 gr soft gel capsule 3 times a day) for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah Diabetes Center

Full name of responsible person

Javad Heshmati

Street address

Songhor Health Center, Songhor, Kermanshah, Iran

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Barij Esans Pharma Industries

Full name of responsible person

Hamidreza Rahmani

Street address

Barij Esans Pharma Industries, Kashan

City

Kashan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Barij Esans Pharma Industries

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Kermanshah University Of Medical Sciences
Full name of responsible person
Javad Heshmati
Street address
Songhor Health Center, Songhor, Kermanshah, Iran
City
Songhor
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah University Of Medical Sciences
Proportion provided by this source
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
Kermanshah University of medical science
Full name of responsible person
Javad Heshmati
Position
Nutrition Master of science
Other areas of specialty/work
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Person responsible for scientific inquiries

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javad.heshmati@gmail.com
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