Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
javad.heshmati@gmail.com

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 hemoglubin(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 questionaire

Intervention groups

1

Description
Intervention group: Comsumption 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

Street address

Songhor Health Center, Songhor, Kermanshah, Iran

City

Songhor

Postal code

6751656363

Phone

+98 83 8423 1045

Fax

Email

Javad.heshmati@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of medical sciences

Full name of responsible person

Javad Heshmati

Position

Master of science

Other areas of specialty/work

Street address

Songhor Health Center, Songhor, Kermanshah, Iran

City

Songhor

Postal code

6751656363

Phone

+98 83 8423 1045

Fax

Email

javad.heshmati@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of medical science

Full name of responsible person

Javad Heshmati

Position

Master of science

Other areas of specialty/work

Street address

Songhor Health Center, Songhor, Kermanshah, Iran

City

Songhor

Postal code

6751656363

Phone

+98 83 8423 1045

Fax

Email

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