Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Efficacy of Nigella sativa L. seed oil in treatment of type 2 diabetic patients: a placebo-controlled clinical trial

Protocol summary

Summary

Nigella sativa seeds are used to treat several diseases including diabetes mellitus in the Iranian traditional medicine. The present study was undertaken to explore the anti-hyperglycemic effect of Nigella sativa (N. sativa) oil in type 2 diabetic patients. Seventy type 2 diabetic patients with fasting blood glucose levels between 140 and 180 mg/dl, body weight between 55 and 75 kg and diabetic disease duration of 2 to 8 years were selected from those diabetic patients referring to Baqiyatallah Hospital. The patients were randomly enrolled in to two groups of 35 each. The study was double-blind (participants and care providers were blind to treatments) and block randomization was used for allocation of patients to the N. sativa oil and the placebo groups. The patients in N. sativa group received 2.5 ml N. sativa oil and the patients in placebo group received similarly 2.5 ml mineral oil two times a day for three months. The patients were advised to continue the drug regimen that was previously prescribed. The fasting and 2 hour postprandial blood glucose and glycosylated hemoglobin (HbA1C) levels were determined in both the groups at baseline and after three months as a main outcome measures.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207301157N7**
Registration date: **2013-08-08, 1392/05/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-08-08, 1392/05/17

Registrant information

Name
Hasan Fallah Huseini
Name of organization / entity
Institute of Medicinal Plants
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Institute of Medicinal Plants and Baqiyatallah University of Medical Sciences

Expected recruitment start date

2012-05-22, 1391/03/02

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Nigella sativa L. seed oil in treatment of type 2 diabetic patients: a placebo-controlled clinical trial

Public title

Efficacy of Nigella sativa L. seed oil in treatment of type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Type 2 diabetic patients with fasting blood glucose levels between 140 and 180 mg/dl; body weight between 55 and 75 kg; age between 34 and 63

years; disease duration of 2 to 8 years; taking no more than two 500 mg metformin and two 5 mg glyburide tablets every day. Exclusion criteria: Patients receiving insulin therapy; patients with cardiac, renal, hepatic and hematological diseases; patients with a history of gallstones or gall bladder surgery; patients using estrogen, steroid, beta-blocker and thiazide drugs; pregnant and breast-feeding women; alcohol consuming and cigarette smoking patients.

Age
From **34 years** old to **63 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

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
Baqiyatallah University of Medical Sciences Ethics Committee

Street address
Vanak square, Molasadra Ave

City
Tehran

Postal code

Approval date
2011-12-03, 1390/09/12

Ethics committee reference number
340/22/س

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E10, E14,

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Fasting blood glucose

Timepoint
At starting of the study and after 3 months

Method of measurement
Blood glucose level was determined in laboratory by commercially available kit

2

Description
Glycosylated hemoglobin (HbA1C)

Timepoint
At starting of the study and after 3 months

Method of measurement
Blood HbA1c level was determined in laboratory by commercially available kit

3

Description
2 hours postprandial blood glucose

Timepoint
At starting of the study and after 3 months

Method of measurement
Blood glucose level was determined in laboratory by commercially available kit

Secondary outcomes

1

Description
BMI (Body mass index)

Timepoint
At starting of the study and after 3 months

Method of measurement
Height and weight using measure tape and weight scales

2

Description
Triglyceride

Timepoint
At starting of the study and after 3 months

Method of measurement
Blood triglyceride level was determined in laboratory by commercially available kit

3

Description
Cholesterol

Timepoint
At starting of the study and after 3 months

Method of measurement
Blood cholesterol level was determined in laboratory by commercially available kit

4

Description
low-density lipoprotein (LDL)
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood LDL level was determined in laboratory by commercially available kit

5

Description
High-density lipoprotein (HDL)
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood HDL level was determined in laboratory by commercially available kit

6

Description
Serum glutamic oxaloacetic transaminase (SGOT)
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood SGOT level was determined in laboratory by commercially available kit

7

Description
Serum glutamic pyruvic transaminase (SGPT)
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood SGPT level was determined in laboratory by commercially available kit

8

Description
Creatinine
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood creatinine level was determined in laboratory by commercially available kit

9

Description
Alkaline phosphatase (ALP)
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood ALP level was determined in laboratory by commercially available kit

Intervention groups

1

Description
Intervention group: Received 2.5 ml N. sativa oil two times a day orally for three months
Category
Treatment - Drugs

2

Description
Placebo group: Received 2.5 ml mineral oil orally two times a day for three months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah University of Medical Sciences
Full name of responsible person
Mahbobah Sadat Hosseini
Street address
Vanak square, Molasadra Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Institute of Medicinal Plants
Full name of responsible person
Reza Hajiaghaee
Street address
Research Complex of Jahad Daneshgahi, ACECR, Kavosh Boulevard, Supa Boulevard, Karaj-Qazvin Highway
City
Karaj
Grant name
روغن سیاه دانه: 84/ 1389/9/10 /س
Grant code / Reference number
1142-33
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Institute of Medicinal Plants
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
Vice chancellor for research, Religion and Medicine Research Center, Baqiyatallah University of Medi
Full name of responsible person
Mahbobeh Sadat Hosseini
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Grant name
روغن سیاه دانه 1/1389/456
Grant code / Reference number
111-306
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Religion and Medicine Research Center, Baqiyatallah University of Medi
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

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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