

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Effect of nigella sativa oil extract on insulin resistance, oxidative stress and inflammatory indices in patients with type 2 diabetes mellitus

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 oil in type 2 diabetic patients. Fifty type 2 diabetic patients with fasting blood glucose levels between 140 and 300 mg/dl, body weight between 55 and 100 kg and diabetic disease duration of 2 to 10 years were selected from those diabetic patients referring to Iranian Diabetes Society. The patients were randomly enrolled in to two groups of 25 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 Nigella sativa oil and the placebo groups. The patients in Nigella sativa group received 500mg Nigella sativa oil and the patients in placebo group received similarly 500mg mineral oil two times a day for two months. The patients were advised to continue the drug regimen that was previously prescribed. fasting blood glucose levels, HbA1c, fasting serum insulin, insulin resistance, serum lipids, TNF-a and Indicators of oxidative stress including total antioxidant capacity, malondialdehyde, catalase, nitric oxide and superoxide dismutase in both groups before and after the intervention will be measured.

General information

Acronym

NS

IRCT registration information

IRCT registration number: **IRCT201307221640N13**

Registration date: **2014-07-06, 1393/04/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-06, 1393/04/15

Registrant information

Name

Parvin Mirmiran

Name of organization / entity

Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Me

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2500

Email address

mirmiran@endocrine.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of nigella sativa oil extract on insulin resistance, oxidative stress and inflammatory indices in patients with type 2 diabetes mellitus

Public title

Effect of nigella sativa oil extract in patients with type 2 diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: subjects between 18-60 years old; type 2 diabetic patients without insulin therapy; patients with history of diabetes more than one year; patients with body mass index between 18 to 35 kg/m². Exclusion criteria: pregnant or lactating women; smokers and alcohol consumers; patients consume antioxidant supplements (vitamin E and C, carotenoids and coQ10); patients with cardiac, hepatic, respiratory and chronic renal diseases; patients with acute or chronic inflammation

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

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 National Nutrition and Food Technology Research Institute

Street address

National Nutrition and Food Technology Research Institute, West Arghavan, Shaheed Farahzadi Blvd. Shahrak-E-Gharb Tehran, Iran. <http://www.nnftri.ac.ir>

City

Tehran

Postal code

474119395

Approval date

2013-11-04, 1392/08/13

Ethics committee reference number

4960/92/پ

Health conditions studied

1

Description of health condition studied

Diabetes type 2

ICD-10 code

E11

ICD-10 code description

Non-insulin dependent diabetes mellitus

Primary outcomes

1

Description

Fasting blood glucose

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

Enzymatic colorimetric

2

Description

Fasting insulin serum

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

ELISA assay

3

Description

HbA1C (Glycosylated hemoglobin)

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

ELISA

4

Description

Insulin resistance

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

HOMA-IR calculation

Secondary outcomes

1

Description

Lipid profiles (TC, TG, LDL-C, HDL-C)

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

Enzymatic methods for TC, TG and HDL-C For LDL-C :
Freidwald's formula: $LDL-C = TC - HDL-C - (TG/5)$

2

Description

TNF-a

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

ELISA

3

Description

IL-1 β

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

ELISA

4

Description

Anthropometric index(weight and Body Mass Index)

Timepoint

before and after 8 weeks intervention

Method of measurement

Analogue scale for weight and weight(Kg)/Square Height for body mass index

5

Description

serum malondialdehyde(MDA)

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

spectrophotometry

6

Description

Nitret oxid(NO)

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

spectrophotometry

7

Description

SOD activity

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

spectrophotometry

8

Description

catalase enzyme activity

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

spectrophotometry

Intervention groups

1

Description

Intervention group: Received 500mg Nigella sativa oil two times a day orally for two months

Category

Treatment - Drugs

2

Description

Placebo group: Received 500mg mineral oil orally two times a day for two months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Diabetes Society

Full name of responsible person

Asadollah Rajab (MD)

Street address

Iranian Diabetes Society, No 46. Ramin Malakuty Avenue, Patris Lomomba Avenue, Sattar Khan Street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Beheshti University of Medical Sciences

Full name of responsible person

Dr Parvin Mirmiran

Street address

National Nutrition and Food Technology Research Institute, West Arghavan, Shaheed Farahzadi Blvd. Shahrak-E-Gharb Tehran

City

Tehran

Grant name

92/6/25

Grant code / Reference number

384

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

Yes

Title of funding source

Vice Chancellor for research of Beheshti 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**

Beheshti University of Medical Sciences

Full name of responsible person

Saeid Hadi

Position

MSc Student in Nutrition Sciences

Other areas of specialty/work**Street address**

National Nutrition and Food Technology Research
Institute, West Arghavan, Shaheed Farahzadi Blvd.
Shahrak-E-Gharb Tehran

City

Tehran

Postal code

193954741

Phone

+98 21 2236 0658

Fax**Email**

s.hadinu@yahoo.com

Web page address**Postal code**

193954741

Phone

+98 21 2236 0658

Fax**Email**

s.hadinu@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Beheshti University of Medical Sciences

Full name of responsible person

Saeid Hadi

Position

MSc Student in Nutrition Sciences

Other areas of specialty/work**Street address**

National Nutrition and Food Technology Research
Institute, West Arghavan, Shaheed Farahzadi Blvd.
Shahrak-E-Gharb Tehran

City

Tehran

Postal code

193954741

Phone

+98 55766659

Fax**Email**

s.hadinu@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Beheshti University of Medical Sciences

Full name of responsible person

Saeid Hadi

Position

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Shahrak-E-Gharb Tehran

City

Tehran

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