Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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,nitret oxid 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

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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, caroteniodes 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
Diabtes 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 (Glycosilated 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-1β
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 Nutritions Sciences
Other areas of specialty/work
Street address
National Nutrition and Food Technology Research Institute, West Arghavan, Shaheed Farahzadi Blvd. Shahrak-E-Gharb Tehran
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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