

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 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 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**  
**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*