

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Assessment the effect of *Nigella sativa* L. seed oil on abnormal sperm parameters in infertile men: a randomized, double-blind, placebo-controlled clinical trial

#### Protocol summary

##### Summary

The aim of this study is to determine the effects of *nigella sativa* oil on the results of semen analysis in infertile men. In this clinical trial, 68 men diagnosed with oligospermia and in the 25 to 40 age range, who have referred to the Infertility Research and Treatment Center in Mahdiah Hospital, are examined. These men should not be azoospermic and they also need to voluntarily consume the mentioned oil. During the treatment, they are not allowed to get any medical treatment. The semen sample of men whose sperm parameters according to WHO are low the normal rate are identified and randomly categorized in one of the control or case groups. Then the oil is prescribed to them. Each one must take a 2.5 c.c -dose, two times a day for 60 days. The control group must take edible paraffin as placebo and visit the center after the treatment period. Semen samples are taken from each group and then examined parameters are rechecked and compared

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201011205204N1**

Registration date: **2011-06-25, 1390/04/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-06-25, 1390/04/04

##### Registrant information

##### Name

Maryam Kolahdooz

##### Name of organization / entity

Shahid Beheshti Medical University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 29 1226 1871

##### Email address

m.kolahdooz@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Beheshti University of Medical Sciences,  
Koodakyar Ave, Daneshju Blvd, Velenjak, Tehran, IRAN

##### Expected recruitment start date

2010-11-22, 1389/09/01

##### Expected recruitment end date

2011-06-22, 1390/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment the effect of *Nigella sativa* L. seed oil on abnormal sperm parameters in infertile men: a randomized, double-blind, placebo-controlled clinical trial

##### Public title

Assessment the effect of *nigella sativa* oil on abnormal sperm parameters of infertile men

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion conditions: 20-45years-old men diagnosed with infertility for more than a year; Volunteer in taking the mixture as treatment and having the consent; Whith no history of renal, hepatic or any chronic illnesses; The

volunteers are not allowed to get any medical treatments; Semen samples, with less than 30% morphology, less than 50% motility and less than type (a) motility. Also with the sperm count below 20 x ml. Exclusion conditions: Men with ozoospermia; gonad abnormalities or varicocele; suffering from urinary retention or infections; those who have taken hormone treatment; evidence of male accessory gland infection; any recent medical or surgical illness; hormone treatment for promoting fertility in the last three months; those who have time limitation (e.g. those whose wives are above 35) and cigarette smoking were excluded

#### **Age**

From **20 years** old to **45 years** old

#### **Gender**

Male

#### **Phase**

2

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **68**

#### **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 Shahid Beheshti University of Medical Sciences

###### **Street address**

Koodakyar Ave, Daneshju Blvd, Velenjak, Tehran, IRAN

###### **City**

Tehran

###### **Postal code**

##### **Approval date**

2011-01-23, 1389/11/03

##### **Ethics committee reference number**

4987-6977

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

infertility

##### **ICD-10 code**

N46

##### **ICD-10 code description**

Male infertility

### **Primary outcomes**

#### **1**

##### **Description**

Morphology

##### **Timepoint**

Before intervention & 2 months after

##### **Method of measurement**

Staining & microscope

#### **2**

##### **Description**

Viscosity

##### **Timepoint**

Before intervention & 2 months after

##### **Method of measurement**

Pipet pastor

#### **3**

##### **Description**

Round cells

##### **Timepoint**

Before intervention & 2 months after

##### **Method of measurement**

Lam & microscope

#### **4**

##### **Description**

Semen volume

##### **Timepoint**

Before intervention & 2 months after

##### **Method of measurement**

Syringe or folkone tube

#### **5**

##### **Description**

Sperm count

##### **Timepoint**

Before intervention & 2 months after

##### **Method of measurement**

Lam & microscope

#### **6**

##### **Description**

Motility

##### **Timepoint**

Before intervention & 2 months after

##### **Method of measurement**

Lam & microscope

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

for Intervention group, nigella sativa oil BD/5 cc .daily use for each patient is 2.5cc oil for 60 days

#### Category

Treatment - Drugs

### 2

#### Description

for control group use placebo 2.5cc BD including edible paraffin for 60 days

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mahdieh infertility center

##### Full name of responsible person

Maryam Kolahdooz

##### Street address

Tehran, shush square, shahrzad avenue, Mahdieh hospital

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Infertility research center of taleghani Shahid Beheshti medical university

##### Full name of responsible person

Miss Sadeghzadeh

##### Street address

Infertility research center of taleghani, Koodakyar Ave., Daneshju Blvd., Velenjak, Tehran, IRAN

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Infertility research center of taleghani Shahid Beheshti medical university

#### 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

Shahid Beheshti Medical University, Koodakyar Ave., Daneshju Blvd., Velenjak, Tehran, IRAN

##### Full name of responsible person

Maryam Kolahdooz

##### Position

Shahid Beheshti Medical University

##### Other areas of specialty/work

##### Street address

Expert

##### City

Rahahan square, Health network, Varamin

##### Postal code

Iran

##### Phone

+98 21 3626 1871

##### Fax

##### Email

mary.kolahdooz@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti Medical University, Koodakyar Ave., Daneshju Blvd., Velenjak, Tehran, IRAN

##### Full name of responsible person

Shahrzad Zadehmodares

##### Position

Doctora

##### Other areas of specialty/work

##### Street address

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti Medical University

**Full name of responsible person**

Maryam Kolahdooz

**Position**

upper expert

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

Rahahan square, Health network, Varamin, Iran

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mary.kolahdooz@yahoo.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*