

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)

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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

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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

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

City

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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

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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