

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effect of *Nigella sativa* supplementation on quality of life, Menopausal symptoms and metabolic syndrome among menopausal women

Protocol summary

Summary

This randomized, double blind, placebo controlled trial, will be conducted to assess the effect of Black seed on quality of life, menopausal symptoms and metabolic syndrome parameters among post menopausal women. Totally, 60 menopausal women aged 45–65 years (at least one year after amenorrhea history) who living in Yasuj are recruited. They shouldn't have history of induced menopause following chemotherapy, radiotherapy or surgery; diagnosed cancers; take hormones or anti hypertensive, antihyperlipidemic or diabetic drugs; history of uncontrolled hypertension, myocardial infarction, stroke or have undiagnosed malignancies. The participants will be randomly divided to two groups of placebo and intervention. The intervention and control group will receive 2 gr of Black seed and placebo for 3 months respectively. We will measure B/P, Weight, Height, BMI, body composition, TG, Cholesterol, LDL, HDL, FBS, 17 β Stradiol, as well as Green Climacteric Scale and SF 36 before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111615414N1**

Registration date: **2014-02-20, 1392/12/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-20, 1392/12/01

Registrant information

Name

Saadat Parhizkar

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 1222 9224

Email address

parhizkar.saadat@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Yasuj University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-04-20, 1393/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of *Nigella sativa* supplementation on quality of life, Menopausal symptoms and metabolic syndrome among menopausal women

Public title

Effect of Black seed on Menopause

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria Menopausal women; aged between 45 to 65 years old; who agreed to participate in the study ;living in yasuj. Exclusion criteria Induced menopause following to surgery, chemotherapy or radiotherapy; taking steroid hormones in previous 3 months; taking anti hypertensive, anti diabetic or anti hyperlipidemic

drugs; history of uncontrolled hypertension, MI, or diagnosed cancers.

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yasuj University of Medical Sciences Ethics Committee

Street address

Yasuj University of Medical Sciences, Motahari Boulevard, Yasuj

City

Yasuj

Postal code

7591994799

Approval date

2013-01-16, 1391/10/27

Ethics committee reference number

91/10/27/8

Health conditions studied

1

Description of health condition studied

Menopausal symptoms

ICD-10 code

O94, O95,

ICD-10 code description

Other obstetric conditions, not elsewhere classified

2

Description of health condition studied

Diabetes

ICD-10 code

E11, E12,

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

Menopausal symptoms

Timepoint

at baseline and end of study

Method of measurement

Green Climacteric Scale

Secondary outcomes

1

Description

Quality of Life

Timepoint

at baseline and at the end of study

Method of measurement

SF-36 questionnaire

2

Description

Cholesterol

Timepoint

at baseline and at the end of study

Method of measurement

mg/dl

3

Description

Triglyceride

Timepoint

at baseline and at the end of study

Method of measurement

mg/dl

4

Description

LDL

Timepoint

at baseline and at the end of study

Method of measurement

mg/dl

5

Description

HDL

Timepoint

at baseline and at the end of study

Method of measurement

mg/dl

6

Description

FBS

Timepoint

at baseline and at the end of study

Method of measurement

mg/dl

7

Description

17 β Stradiol

Timepoint

at baseline and at the end of study

Method of measurement

pg/dl

8

Description

FSH

Timepoint

at baseline and at the end of study

Method of measurement

miu/ml

9

Description

LH

Timepoint

at baseline and at the end of study

Method of measurement

miu/ml

10

Description

Blood pressure

Timepoint

at baseline and at the end of study

Method of measurement

mmHg

11

Description

weight

Timepoint

at baseline and at the end of study

Method of measurement

kg

12

Description

Height

Timepoint

at baseline and at the end of study

Method of measurement

cm

13

Description

BMI

Timepoint

at baseline and at the end of study

Method of measurement

kg/m²

14

Description

Body composition

Timepoint

at baseline and at the end of study

Method of measurement

Percent

Intervention groups

1

Description

Intervention group: Nigella sativa Capsule 2gr/day

Category

Prevention

2

Description

Control Group: Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zir Tole health Section, Shahid Ashrafi Isfahani Health Center

Full name of responsible person

Fariba Mohammadi

Street address

Alley 2, Golzar Shohada Street, Zir Tole

City

Yasuj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Yasuj University of Medical Sciences

Full name of responsible person

Dr Abd Mohammad Moosavi

Street address

Vice chancellor for research, Yasuj University of Medical Sciences, Motahari Boulevard, Yasuj

City

Yasuj

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Yasuj 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**

Yasuj University of Medical Sciences

Full name of responsible person

Saadat Parhizkar

Position

PhD/ Assistant Professor

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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