

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigation of the Effect of Capsule containing Black Seed (*Nigella Sativa L.*) and Palm Date Spathe in comparison with Education based on Information-Motivation-Behavior (IMB) Model on Bone Density of Postmenopausal Women

#### Protocol summary

##### Study aim

The aim of this study is to determine the Effect of Capsules containing Black Seed and Palm Date Spathe in comparison with Education based on Information Motivation Behavior (IMB) Model on Bone Density of Postmenopausal Women

##### Design

Randomized Clinical Trial, With control group, No blinding, Single phase on 105 samples, Allocation by Block Randomization Method and Using R Statistical Software

##### Settings and conduct

After sampling in the Rheumatology Clinic of Shefa Kerman Hospital with Convenience Sampling Method, The samples are allocated to 7 blocks of 15 numbers and in 5 groups. Interventions will include Common treatment, The capsule of this study and Education. The control group will not have any intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria; age 45-65 years and Normal Menopause. Non-Entry criteria; Diseases affecting Bone Metabolism, Underlying causes of Prolonged Immobility, History of Bone Fracture, Taking any of the Osteoporosis Treatment Drugs, Use of Tibolone or Hormone therapy, Use of drugs affecting Bone Metabolism, Treatment with other Phytoestrogens, History of Allergy to Black Seed or Palm Date Spathe, Smoking or Alcohol use, The 10-year Fracture Risk is higher than the permissible threshold

##### Intervention groups

The Education will consist of 4 sessions of 1.5 hours once a week. The second group will have a daily Capsule containing Black Seed and Palm Date Spathe and in the third group, the Common treatment is 1500 mg Calcium Tablet daily and 50000 IU Vitamin D3 Tablet every two weeks. In the fourth group, The Common treatment and Capsules will be used at the same time and the control

group will not receive any type of intervention.

##### Main outcome variables

Bone Density

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221113056484N1**

Registration date: **2022-12-10, 1401/09/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-12-10, 1401/09/19**

Update count: **0**

##### Registration date

2022-12-10, 1401/09/19

##### Registrant information

##### Name

Zahra Bamorovat

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3272 0504

##### Email address

za.bamorovat@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-06, 1401/09/15

##### Expected recruitment end date

2023-03-06, 1401/12/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigation of the Effect of Capsule containing Black Seed (Nigella Sativa L.) and Palm Date Spathe in comparison with Education based on Information-Motivation-Behavior (IMB) Model on Bone Density of Postmenopausal Women

**Public title**

Effect of Capsule containing Black Seed (Nigella Sativa L.) and Palm Date Spathe in comparison with Education based on Information-Motivation-Behavior (IMB) Model on Bone Density of Postmenopausal Women

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 45-65 years Normal Menopause, When the person is Amenorrhoeic for at least one year and is not the result of Surgery, Chemotherapy or Premature Menopause Informed Consent to participate in the Study

**Exclusion criteria:**

Diseases affecting Bone Metabolism (Endocrine: Hypopituitarism, Growth Hormone Deficiency, Hyperprolactinemia, Hypercortisolism (Cushing's Disease and Syndrome), Thyroid Disorders (Hypothyroidism and Hyperthyroidism), Hyperparathyroidism, Diabetes Mellitus type 1 and 2, Untreated Hypogonadism, Primary Hyperaldosteronism. Gastrointestinal: Anorexia Nervosa, Bulimia Nervosa, Bariatric Surgery, Malabsorption, Crohn's Disease, Ulcerative Colitis, Celiac Disease, Chronic Diarrhea, Stomach and Duodenal Ulcers under treatment or a history of their association with Gastrointestinal Bleeding. Autoimmune: Rheumatoid Arthritis, Ankylosing Spondylitis, Systemic Lupus Erythematosus. Connective Tissue Disorders: Ehlers-Danlos Syndrome, Marfan Syndrome. Hematology: Beta Thalassemia Major. Other: Acute or Chronic disease (Liver, Kidney or Heart Disease), Types of Cancer, Hypo/Hypercalcemia. Severe Psychiatric Disorders including Chronic Anxiety and Depression Disorders (For more than 2 years) Underlying causes of Prolonged Immobility (Such as Spinal Cord Injury, Parkinson's Disease, Stroke, Muscular Dystrophy, Ankylosing Spondylitis) History of Bone Fracture in the last 3 years Taking any of the Osteoporosis Treatment Drugs (Antiresorptive/Anabolic) Use of Tibolone or any type of Hormone Therapy (Systemic or Local) three months before the intervention Use of Anticonvulsants, Glucocorticoids (more than 5 mg Prednisolone per day or use for three months or more), Chemotherapy Drugs, Antiretrovirals, Proton Pump Inhibitors, Cyclic Diuretics, Thiazolidinediones, Selective Serotonin Reuptake Inhibitors (SSRIs) for at least 6 months, Benzodiazepines, Barbiturates, Beta-Blockers for more than 5 years, Statins, Unfractionated Heparin/Low Molecular Weight Heparin/Warfarin and Calcineurin Inhibitors Treatment

with other Phytoestrogens three months before the intervention History of Allergy to Black Seed or Palm Date Spathe History of Smoking more than 20 Cigarettes per day Consumption of Alcoholic Beverages 3 units or more per day (Each unit is equivalent to 10 ml or 8 grams) The 10-year Fracture Risk is higher than the permissible threshold for delaying routine treatments

**Age**

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

**Gender**

Female

**Phase**

0

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **105**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Eligible Patients will be selected by Convenience Sampling Method. Block Randomization Method (Bone Density Status: Normal, Osteopenia and Osteoporosis) will be used to allocate the samples to 5 groups. According to the number of groups and the size of total sample, 7 blocks of 15 numbers will be selected. The Randomization List will be created using R Statistical Software and the block.random() Command.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Kerman University of Medical Sciences

**Street address**

Kerman University of Medical Sciences, Haft Bagh Alavi Highway

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Approval date**

2022-11-19, 1401/08/28

**Ethics committee reference number**

IR.KMU.REC.1401.310

## Health conditions studied

### 1

#### Description of health condition studied

Bone Density of Postmenopausal Women

#### ICD-10 code

M81.0

#### ICD-10 code description

Age-related osteoporosis without current pathological fracture

## Primary outcomes

### 1

#### Description

The result of Dual-Energy X-ray Absorptiometry (T-Score, Z-Score and Bone Mineral Density)

#### Timepoint

Before starting the study and 6 months later

#### Method of measurement

Dual-Energy X-ray Absorptiometry Scanner

### 2

#### Description

Serum Calcium level

#### Timepoint

Before starting the study and 6 months later

#### Method of measurement

Laboratory kit

### 3

#### Description

Serum Phosphorus level

#### Timepoint

Before starting the study and 6 months later

#### Method of measurement

Laboratory kit

### 4

#### Description

Serum Alkaline Phosphatase level

#### Timepoint

Before starting the study and 6 months later

#### Method of measurement

Laboratory kit

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first intervention group: The Education will consist of 4 sessions of 1.5 hours once a week based on

Information Motivation Behavior Model. The content of these sessions is designed to increase Information, Motivation, Self-Efficacy and Decisive Behavior in the field of Bone Density of Postmenopausal Women.

#### Category

Treatment - Other

### 2

#### Description

The second intervention group: Will have an oral Capsule containing 500 mg Black Seed and Palm Date Spathe daily for 6 months which was designed at the Faculty of Pharmacy, Kerman University of Medical Sciences.

#### Category

Treatment - Drugs

### 3

#### Description

The third intervention group: The Common treatment is 1500 mg Calcium Tablet daily and 50000 IU Vitamin D3 Tablet every two weeks for 6 months.

#### Category

Treatment - Drugs

### 4

#### Description

The fourth intervention group: The Common treatment and Capsule containing Black Seed and Palm Date Spathe will be used at the same time for 6 months.

#### Category

Treatment - Drugs

### 5

#### Description

Control group: Will not receive any type of treatment.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat Clinic, Rheumatology Clinic of Shafa Hospital, Kerman

##### Full name of responsible person

Dr. Sareh Sadat Ebrahimi

##### Street address

Somayeh Cross(Tahmasb Abad)

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913555

##### Phone

+98 34 3132 5700

##### Email

za.bamorovat@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Abbas Pardakhty

**Street address**

Kerman University of Medical Sciences, Haft Bagh  
Alavi Highway

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Phone**

+98 34 3132 5690

**Email**

za.bamorovat@gmail.com

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

Yes

**Title of funding source**

Kerman University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Masumeh Ghazanfarpour

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Razi Faculty of Nursing and Midwifery, Kerman  
University of Medical Sciences, Haft Bagh Alavi  
Highway

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Phone**

+98 34 3132 5206

**Email**

m.ghazanfarpour@kmu.ac.ir

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Masumeh Ghazanfarpour

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Razi Faculty of Nursing and Midwifery, Kerman  
University of Medical Sciences, Haft Bagh Alavi  
Highway

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Phone**

+98 34 3132 5206

**Email**

m.ghazanfarpour@kmu.ac.ir

## Person responsible for updating data

**Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Zahra Bamorovat

**Position**

Master's Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Razi Faculty of Nursing and Midwifery, Kerman  
University of Medical Sciences, Haft Bagh Alavi  
Highway

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Phone**

+98 34 3132 5206

**Email**

ba.aug97@gmail.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Information on the main outcome

**When the data will become available and for how long**

6 months after publication of the article

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

To develop Bone Density management programs and only with Academic Affiliation

**From where data/document is obtainable**

Dr. Masumeh Ghazanfarpour  
m.ghazanfarpour@kmu.ac.ir

**What processes are involved for a request to access data/document**

Sending an email to Dr. Masoumeh Ghazanfarpour and after going through the process of verifying the applicant's identity for two weeks, an answer will be given.

**Comments**