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

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Iran (Islamic Republic of)

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Abbas Pardakhty
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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
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
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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