

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation the effect of oral capsule of Peganum harmala seed on bone density in menopausal women prone to osteoporosis

Protocol summary

Summary

The purpose of this study was to determine the effect of oral capsule of Peganum harmala seed on bone density in menopausal women prone to osteoporosis. This study is a clinical trial of phase 3, single-centered. 100 patients with inclusion Criteria: Postmenopausal women who at least 12 month past after amenorrhea without correlation with pregnancy, breast-feeding or other hormonal disorders ;prone to osreoprosis with T score of less than 2.5 in bone density measurement. Exclusion criteria: Gastrointestinal absorption disorder; Thyroid patients; Kidney and liver diseases are divided into two groups of 50. In the first group: receive peganum harmala capsules 500 mg twice daily with routine treatment and the control group received only routine medications. Three months later, bone densitometry is done . The T score determines response to treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017091910222N12**

Registration date: **2017-10-22, 1396/07/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-22, 1396/07/30

Registrant information

Name

Zahra Keivani

Name of organization / entity

Shahrekord University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1222 0016

Email address

keivani@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Science

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of oral capsule of Peganum harmala seed on bone density in menopausal women prone to osteoporosis

Public title

Evaluation the effect of oral capsule of Peganum harmala seed on bone density in menopausal women prone to osteoporosis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Postmenopausal women who at least 12 month past after amenorrhea without correlation with pregnancy, breast-feeding or other hormonal disorders ;prone to osreoprosis with T score of less than 2.5 in bone density measurement. Exclusion criteria: Gastrointestinal absorption disorder; Thyroid patients; Kidney and liver diseases

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization not done

Secondary Ids

empty

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

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Kashani street, shahrekord university of medical sciences, shahrekord

City

Shahrekord

Postal code**Approval date**

2017-03-12, 1395/12/22

Ethics committee reference number

IR.SKUMS.REC.1395.331

Health conditions studied**1****Description of health condition studied**

osteoprosis

ICD-10 code

M80-M94

ICD-10 code description

Osteopathies and chondropathies

Primary outcomes**1****Description**

T score

Timepoint

3 month after intervention

Method of measurement

Bondensitometry

Secondary outcomes

empty

Intervention groups**1****Description**

the first group: receive peganum harmala capsules 500 mg twice daily with routine treatment

Category

Treatment - Drugs

2**Description**

the second group receive only routine treatment .

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kashani hospital in Shahrekord

Full name of responsible person

Morteza Dehghan

Street address

Parastar street, Kashani Hospital of Shahrekord University of Medical Sciences, shahrekord

City

shahrekord

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research of Shahrekord University of Medical Science

Full name of responsible person

Dr. Kamal Solati

Street address

Kashani street, shahrekord university of medical sciences, shahrekord

City

Shahrekord

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 of Shahrekord University of Medical Science

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

Shahrekord University of Medical Sciences

Full name of responsible person

Morteza Dehghan

Position

Ortopedic specialist, Associate Professor

Other areas of specialty/work

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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