

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of Curcumin on Bone Turnover markers and Bone Densitometry characteristics in Post Menopausal Women with Osteoporosis

Protocol summary

Summary

The aim of this study is to investigate the effects of Curcumin in combination with Alendronate on bone loss and bone turnover markers in Post Menopausal women's with Osteoporosis. This study conducted is a double blind clinical trial. Inclusion criteria: Age between 55- 65 years, At least 5 years after the last menstrual period and Osteoporosis. Exclusion criteria: any secondary cause of osteoporosis such as metabolic or endocrine disease, affecting bone drugs such as Bisphosphonates, Calcium and Vitamin D, Cardiovascular, Cerebrovascular, Rheumatologic disease, Alcohol and or smoking . Patients divided into four groups: control, Curcumin, Curcumin + Alendronate and Alendronate. Curcumin at a dose 110 mg daily and Alendronate at a dose of 5 mg per kg per day prescribed for 12 months, level of biochemical markers related to bone turnover and also densitometry features of patients were performed for all patients at baseline and 12 months after the intervention. Statistical analysis was performed end-to interpret result.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030424308N1**

Registration date: **2016-12-04, 1395/09/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-04, 1395/09/14

Registrant information

Name

Mohammad Reza Hafezi Ahmadi

Name of organization / entity

Ilam University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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hafezi-m@medilam.ac.ir

Recruitment status

Recruitment complete

Funding source

Ilam University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-06-09, 1395/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Curcumin on Bone Turnover markers and Bone Densitometry characteristics in Post Menopausal Women with Osteoporosis

Public title

The effect of Curcumin on Osteoporosis in Post Menopausal Women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 55- 65 years, At least 5 years after the last menstrual period and Osteoporosis. Exclusion criteria: any secondary cause of osteoporosis such as metabolic or endocrine disease, affecting bone drugs such as Bisphosphonates, Calcium and Vitamin D, Cardiovascular, Cerebrovascular, Rheumatologic

disease, Alcohol and or smoking

Age
From **55 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ilam University of Medical Sceince

Street address

Iran, Ilam, Ilam University of Medical Science,
Banganjab, Daneshjoo boulevard

City

Ilam

Postal code

Approval date

2016-04-25, 1395/02/06

Ethics committee reference number

ir.medilam.rec.1395.187

Health conditions studied

1

Description of health condition studied

Osteoporosis

ICD-10 code

M81.0

ICD-10 code description

Postmenopausal osteoporosis

Primary outcomes

1

Description

Bone-specific alkaline phosphatase

Timepoint
Baseline and after 12 months

Method of measurement
laboratory kit

2

Description

Osteocalcin

Timepoint

Baseline and after 12 months

Method of measurement

laboratory kit

3

Description

Type 1 of Telopectides

Timepoint

Baseline and after 12 months

Method of measurement

laboratory kit

4

Description

Femoral Neck Bone Mineral Density

Timepoint

Baseline and after 12 months

Method of measurement

laboratory kit

5

Description

Total Hip Bone Mineral Density

Timepoint

Baseline and after 12 months

Method of measurement

laboratory kit

6

Description

Lumbar Spine Bone Mineral Density

Timepoint

Baseline and after 12 months

Method of measurement

laboratory kit

Secondary outcomes

empty

Intervention groups

1

Description

Control group : No intervention

Category

Treatment - Drugs

2

Description

Alendronate groups: Alendronate is administered at a dose of 5 mg/kg of body weight per day for 12 months .

Category

Treatment - Drugs

3

Description

Alendronate + curcumin group: alendronate at a dose of 5 mg/kg of body weight per day for 12 months + curcumin at a dose of 110 mg/kg of body weight per day for 12 months

Category

Treatment - Drugs

4

Description

Curcumin group: curcumin at a dose of 110 mg/kg of body weight per day for 12 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology and Obstetrics Clinic of Mostafa Khomeini in Ilam city

Full name of responsible person

Mohammad Reza Hafezi Ahmadi

Street address

Ilam University of Medical Sciences, Research Blvd, Ban Ganjab, Ilam city, Ilam Province, Iran

City

Ilam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Kourosh Sayemiri

Street address

Ilam University of Medical Sciences, Research Blvd, Ban Ganjab, Ilam city, Ilam Province, Iran

City

Ilam

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Mohammad Reza Hafezi Ahmadi

Position

Pathologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Fatemeh Khanizadeh

Position

Obstetricians

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Fatemeh Khanizadeh

Position

Obstetricians

Other areas of specialty/work**Street address**

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Web page address**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