

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effect of Folic Acid on Bone Metabolism in Post-Menopausal Osteoporotic Women: A Randomized Double Blind Clinical Trial

Protocol summary

Summary

In spite of several studies, the impact of homocysteine level and folic acid supplementation on biochemical bone markers has not been established. In this study we aimed to find out the impact of folic acid supplementation and homocysteine on bone bio-markers in 6 months. Forty postmenopausal osteoporotic women enrolled in the study. All participants randomized to take folic acid tablet 1 mg or placebo on daily basis. At baseline, 3 months and 6 months post intervention the level of homocysteine, vitamin B12, and bone bio-markers were measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042217385N1**
Registration date: **2014-05-20, 1393/02/30**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-20, 1393/02/30

Registrant information

Name

Pooneh Salari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6641 9661

Email address

salari@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-07-01, 1390/04/10

Expected recruitment end date

2012-07-01, 1391/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Folic Acid on Bone Metabolism in Post-Menopausal Osteoporotic Women: A Randomized Double Blind Clinical Trial

Public title

Effect of Folic Acid on Bone Metabolism: A Randomized Double Blind Clinical Trial in Postmenopausal osteoporosis Women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Age= 50-60yrs; Postmenopausal Women; Osteoporosis. Exclusion Criteria: History of Cancer; Acute Infection; Endocrinologic Diseases; Taking Medicines Affecting Bone Metabolism Such As Corticosteroids;Gonadotropine Releasing Hormone (GnRH) Analogues; Anticonvulsant Drugs; Heparin; Aluminum Containing Antacids; Thyroid Hormones.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Endocrinology and Metabolism Research Institute of the Tehran University of

Street address

5th Floor, Shariati Hospital, Al-e-Ahmad High Way

City

Tehran

Postal code

Approval date

2011-03-02, 1389/12/11

Ethics committee reference number

00102

Health conditions studied

1

Description of health condition studied

Osteoporosis

ICD-10 code

M81.0

ICD-10 code description

Senile Osteoporosis

Primary outcomes

1

Description

Pyridinoline

Timepoint

At Baseline, 3 and 6 Months Later

Method of measurement

µg/mmol cr

2

Description

Osteocalcin

Timepoint

At Baseline, 3 and 6 Months Later

Method of measurement

ng/ml

3

Description

Bone Alkaline Phosphatase

Timepoint

At Baseline, 3 and 6 Months Later

Method of measurement

U/L

4

Description

U β Cross Laps

Timepoint

At Baseline, 3 and 6 Months Later

Method of measurement

µg/mmol cr

5

Description

Bone density

Timepoint

Before

Method of measurement

Gm/cm²

Secondary outcomes

empty

Intervention groups

1

Description

Folic Acid Tablet 1 mg/day

Category

Prevention

2

Description

Placebo 1 Tablet Per Day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Center, Endocrinology and Metabolism

Research Institute of Tehran University of Medical Sci
Full name of responsible person
Miss Shirazi
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Mehrdad
Street address
5th Floor, Shariati Hospital, Al-e-Ahmad High Way
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran 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
Medical Ethics and History of Medicine Research
Center of Tehran University of Medical Sciences
Full name of responsible person
Pooneh Salari
Position
Specialist in Clinical Pharmacy, Assistant Professor
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Person responsible for scientific inquiries

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Person responsible for updating data

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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