Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effects of oligopin supplementation on the turnover of bone formation and antioxidant changes in postmenopausal osteopenic women: A randomized double-blind clinical trial with placebo-concurrent controls

Protocol summary

Study aim

To investigate the effects of oligopin on bone turnover markers and plasma and peripheral mononuclear cells oxidative stress in postmenopausal women with osteopenia in a double-blind randomized clinical trial.

Design

A Randomized, Double-blind, Placebo-Controlled Trial

Settings and conduct

Placebo and Oligopin® capsules were distributed by the site research officer who is unaware of the contents of the packages. Patients, health care clinicians and research staff involved in data collection and statistical analysis were blinded and unaware of the randomization and intervention of the patients.

Participants/Inclusion and exclusion criteria

The inclusion criteria were postmenopausal women with a diagnosis of osteopenia (-2.5 SD ≤ T-score ≤ -1 SD), age between 50-65, and having equal physical activities, complementary and pediatric therapies for at least three months before study entry. The subjects were excluded if they had body mass index ≥ 40 kg/m2, the occurrence of any visible side effects of the intervention, fracture report during the follow-up period, refusal to continue the trial, history of acute and chronic disorders, and current smoking and alcohol intake. women receiving drugs affecting on bone metabolism were not permitted to participate in this study.

Intervention groups

Oligopin ,150 mg , once daily, 12 week placebo, 150 mg, once daily,12 weeks

Main outcome variables

The levels of osteocalcin and carboxy-terminal collagen type I in plasma oxidative stress markers such as total antioxidant capacity, malondialdehyde, and protein carbonyl, total thiol content are evaluated. Furthermore, oxidative stress will be evaluated in peripheral blood mononuclear cells by measurement of expression and activity of magnesium superoxide dismutase, catalase in PBMCs, and Plasma and Nuclear factor (erythroid-derived 2)-like 2 expressions in PBMCs.

General information

Reason for update

we made a mistake in writing the expected recruitment start date because it had been written before the registration date by mistake. Since the manuscript is ready for submission, other parts including actual recruitment start date and end date, blinding, and allocation was completed. The recruitment center was also changed from Shariarti Hospital to Shahid AkbarAbadi Hospital because of the impairment of Dual-energy X-ray absorptiometry (DEXA). Since the trial has been completed, other parts were updated.

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060334308N1**
Registration date: **2017-08-20, 1396/05/29**
Registration timing: **prospective**

Last update: **2020-05-16, 1399/02/27**
Update count: **1**

Registration date

2017-08-20, 1396/05/29

Registrant information

Name

Solaleh Emamgholipour

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6443 2623

Email address

semamgholipour@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-08-25, 1396/06/03

Expected recruitment end date

2018-08-15, 1397/05/24

Actual recruitment start date

2018-02-01, 1396/11/12

Actual recruitment end date

2018-12-01, 1397/09/10

Trial completion date

2019-03-01, 1397/12/10

Scientific title

Evaluating the effects of oligopin supplementation on the turnover of bone formation and antioxidant changes in postmenopausal osteopenic women: A randomized double-blind clinical trial with placebo-concurrent controls

Public title

Evaluating the effects of oligopin supplementation on the turnover of bone formation and antioxidant changes in postmenopausal osteopenic women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Postmenopausal women; Aged between 50-65; Diagnosis of osteopenia based on Tscore (-2.5 SD ≤ Tscore ≤ -1 SD) To have equal physical, pediatric and complementary therapies for at least three months before entrance to study

Exclusion criteria:

The subjects were excluded if they had body mass index ≥ 40 kg/m2, the occurrence of any visible side effects of the intervention,fracture report during the follow-up period, refusal to continue the trial, history of bone disorders, history of any malignancy, diabetes, kidney failure, hepatic disease, skeletal disorders, systemic inflammatory diseases, rheumatologic disorders, degenerative joint diseases, hyperthyroidism, Cushing's syndrome, history of gastrointestinal disease or bleeding, motor disabilities, untreated psychiatric illnesses such as Alzheimer's disease, Parkinson's disease, psychosis, and current smoking and alcohol intake.As for the history of the use of drugs, women receiving osteoporosis drugs (e.g. estrogen receptor-selective agonists / antagonists, bisphosphonates, PTH, and alternative HRTs), anticonvulsants (i.e. phenobarbital, phenytoin, sodium valproate), nonsteroidal anti-inflammatory drugs (i.e. naproxen, aspirin, and ibuprofen), thiazides, diuretics, glucocorticoids were not permitted to participate in this study.

Age

From **50 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Actual sample size reached: **43**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed for all participants based on age (50–55, 55–60, and 60– 65 years old) and BMI (BMI more than 27.50 kg/m2and less than 27.50 kg/m2) to minimize any bias.

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo and Oligopin® capsules were distributed by the site research officer who is unaware of the contents of the packages. Patients, health care clinicians and research staff involved in data collection and statistical analysis were blinded and unaware of the randomization and intervention of the patients. It should be noted that capsules containing pine bark extract and placebo were identical in appearance, size, and color.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences (TUMS)

Street address

Tehran University of Medical Sciences (TUMS)

City

Tehran

Province

Tehran

Postal code

1416634793

Approval date

2017-05-23, 1396/03/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.2372

Health conditions studied

1

Description of health condition studied
Osteopenia
ICD-10 code
M 81.0
ICD-10 code description
Postmenopausal osteoporosis

Primary outcomes

1

Description
Carboxy terminal collagen type I
Timepoint
Before and third month after intervention
Method of measurement
ELISA

2

Description
Osteocalcin
Timepoint
Before and third month after intervention
Method of measurement
ELISA

3

Description
Osteocalcin/CTX1 ratio
Timepoint
Before and third month after interventio
Method of measurement
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Secondary outcomes

1

Description
MnSOD activity in plasma and peripheral blood mononuclear cells (PBMCs) in postmenopausal osteopenic women and placebo-concurrent controls
Timepoint
At first of study,third month
Method of measurement
spectrophotometer

2

Description
Catalse activity in plasma and peripheral blood mononuclear cells (PBMCs) in postmenopausal osteopenic women and placebo-concurrent controls
Timepoint
Before intervention,third month after intervention
Method of measurement
spectrophotometer

3

Description
NrF2 gene expression in peripheral blood mononuclear cells (PBMCs) in postmenopausal osteopenic women and placebo-concurrent controls
Timepoint
Before intervention,third month after intervention
Method of measurement
Real-Time PCR

4

Description
MnSOD expression in peripheral blood mononuclear cells (PBMCs) in postmenopausal osteopenic women and placebo-concurrent controls
Timepoint
Before intervention,third month after intervention
Method of measurement
real-time PCR

5

Description
Catalase expression in peripheral blood mononuclear cells (PBMCs) in postmenopausal osteopenic women and placebo-concurrent controls
Timepoint
Before intervention,third month after intervention
Method of measurement
real-time PCR

6

Description
MDA plasma levels in postmenopausal osteopenic women and placebo-concurrent controls
Timepoint
Before intervention,third month after intervention
Method of measurement
spectrophotometer

7

Description
Plasma levels of total antioxidant capacity in postmenopausal osteopenic women and placebo-concurrent controls
Timepoint
Before intervention,third month after intervention
Method of measurement
spectrophotometer

8

Description
Evaluating plasma levels of protein carbonylation in postmenopausal osteopenic women and placebo-concurrent controlsP
Timepoint
Before intervention,third month after intervention
Method of measurement
spectrophotometer

9

Description
Evaluating plasma levels of total thiol contents in postmenopausal osteopenic women and placebo-concurrent controls
Timepoint
Before intervention,third month after intervention
Method of measurement
spectrophotometer

Intervention groups

1

Description
placebo, 150 mg,once daily,12 weeks
Category
Treatment - Drugs

2

Description
Oligopin ,150 mg ,once daily, 12 week
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbarabadi hospital.
Full name of responsible person
Afsaneh Ghasemi-Solaleh Emamgholipour
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
Tehran 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
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Solaleh Emamgholipour
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Assistant Professor
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Data are available on request to the authors after manuscript publication.
When the data will become available and for how long
when summary data are published
To whom data/document is available
This is only available for people working
Under which criteria data/document could be used

From where data/document is obtainable
Corresponding authors' email addresses
What processes are involved for a request to access data/document
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Comments