

# 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 ( $-2.5 \text{ SD} \leq \text{T-score} \leq -1 \text{ SD}$ ), 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  $\geq 40 \text{ kg/m}^2$ , 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 ( $-2.5 \text{ SD} \leq \text{Tscore} \leq -1 \text{ SD}$ ) 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  $\geq 40 \text{ kg/m}^2$ , 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/m<sup>2</sup> and less than 27.50 kg/m<sup>2</sup>) 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**

Catalase 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

##### Street address

Mowlavi St., Ferdows Gardens Statio

##### City

Tehran

##### Province

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##### Postal code

1168743514

##### Phone

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##### Email

akbarabadihosp@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Ali Sahraian

##### Street address

Faculty of Medicine, Tehran University of Medical Sciences, Poursina avenue Tehran Tehran Iran

##### City

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##### Province

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##### Postal code

1416753955

##### Phone

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##### Email

gsia@tums.ac.ir

##### Web page address

##### 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

Tehran University of Medical Sciences

##### Full name of responsible person

Solaleh Emamgholipour

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Biochemistry

##### Street address

Department of Biochemistry, Faculty of Medicine, Tehran University of Medical Sciences, Tehran, Iran

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##### Phone

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##### Email

semamgholipour@sina.tums.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Department of Biochemistry, Faculty of Medicine,  
Tehran University of Medical Sciences, Tehran, Iran

**Full name of responsible person**

Solaleh Emamgholipour

**Position**

PhD,Clinical Biochemistry,Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

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+98 982164432623

**Fax****Email**

semamgholipour@sina.tums.ac.ir

**Web page address****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**

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**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****Person responsible for updating data****Contact****Name of organization / entity**

Department of Biochemistry, Faculty of Medicine,  
Tehran University of Medical Sciences, Tehran, Iran

**Full name of responsible person**

Solaleh Emamgholipour

**Position**

PhD,Clinical Biochemistry,Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

**Street address**

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