

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### On the consideration and comparison of Panjangosht (*Vitex agnus-castus*) and Maryamgoli (*Salvia officinalis*) effects on the osteogenic factors and physical and emotional symptoms in menopausal women

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Summary

**Objectives:** In this study, alkaline phosphatase, osteocalcin, carboxy-terminal telopeptides of type I collagen, calcium, phosphorus, vitamin D, physical and psychological symptoms before and after treatment in vitex and sage extract group compared with the control group. **Design:** In this double-blind study of 100 postmenopausal women referred to hospital BMD Namazee(single core) by permutation block divided into three groups and blinding The idea is that participants with the contacts did not have the help of researcher Tablets black codes and put in jars to the researcher does not know what a pill each canister. **Setting and conduct:** First, personal information forms and a questionnaire about Menopause Rating Scale (MRS) and tests of osteogenic factors is performed and the above process is repeated after 3 months of intervention. **Inclusion criteria:** are osteopenic postmenopausal women who received calcium and vitamin D supplementation but do not receive other effective drugs on bone density. **Interventions:** the first intervention group is given, daily, one Agnugol tablets, 3.2- 4.8Mg(extract of VAC), the second group is given, daily, three Salvigol tablets, 100 Mg(*Salvia officinalis* extract), and the third group is given each day three placebo tablets.. Agnugol and Salvgl tablets are products Goldarou Company of Esfahan .main outcome: osteogenic factors - physical and mental symptoms.

Last update:

Update count: **0**

#### Registration date

2016-04-26, 1395/02/07

#### Registrant information

##### Name

Marzieh Akbarzadeh

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1647 4254

##### Email address

akbarzadm@sums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

Vice chancellor for research Shiraz University of Medical Sciences

#### Expected recruitment start date

2016-04-20, 1395/02/01

#### Expected recruitment end date

2016-07-22, 1395/05/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

On the consideration and comparison of Panjangosht (*Vitex agnus-castus*) and Maryamgoli (*Salvia officinalis*)

#### General information

##### Acronym

comparison of Panjangosht and Maryamgoli effects on the osteogenic factors and physical and

##### IRCT registration information

IRCT registration number: **IRCT2015111713940N2**

Registration date: **2016-04-26, 1395/02/07**

effects on the osteogenic factors and physical and emotional symptoms in menopausal women

#### Public title

effect vitex and sage on osteogenic factors and physical and emotional symptoms in menopausal women

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria :1) Menopausal women, 2) Women willing to cooperate in this study and presented their written consent form, 3) These women should not suffer from diseases related to liver, kidney, thyroid, parathyroid, intestine and bone..... in which they receive special medicines which affect the bone density, 4)They should not use any kinds of hormonal medicines, 5) Menopausal women who are osteopenic and receive supplementary Calcium and vitamin D, but they do not receive treatment with other with other effective hormonal medicines which affect the bone density (these medicines are mostly used by osteoprose patients), 6) They should not be sensitive to herbal medicines.  
.Exclusion criteria:1) Allergic reaction to medicine, 2) Detection of a patient, during the study, who needs to use the medicine effective on bone density.

#### Age

No age limit

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: **100**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

Block permutation methods

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of shiraz university of Medical Sciences

###### Street address

Shiraz - Zand Street - Next to the Red Crescent -

Sakhtmtn Central University - Class 7 - Research

#### City

Shiraz

#### Postal code

1978 -71345

#### Approval date

2016-01-24, 1394/11/04

#### Ethics committee reference number

IR.SUMS.REC.1394.185

### Health conditions studied

#### 1

##### Description of health condition studied

-

##### ICD-10 code

-

##### ICD-10 code description

-

#### 2

##### Description of health condition studied

-

##### ICD-10 code

-

##### ICD-10 code description

-

### Primary outcomes

#### 1

##### Description

osteogenic factors

##### Timepoint

At the beginning and end of the study

##### Method of measurement

Blood test

### Secondary outcomes

#### 1

##### Description

physical and emotional symptoms

##### Timepoint

At the beginning and end of the study

##### Method of measurement

the questionnaire about Menopause Rating Scale(MRS)

### Intervention groups

#### 1

##### Description

the first intervention group is given, daily, one Agnugol tablets, 3.2- 4.8 Mg for 3 months( product Goldarou Company of Esfahan)

##### Category

Treatment - Drugs

## 2

### Description

the second intervention group is given, daily, three Salvigol tablets, 100 Mg for 3 months ( product of Goldarou Company of Esfahan)

### Category

Treatment - Drugs

## 3

### Description

In control group is given each daily three placebo tablets for 3 months

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Namazee hospital

##### Full name of responsible person

mohammadali tadayon

##### Street address

shiraz-Namazee hospital

##### City

shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice President of Research Shiraz University of Medical Sciences

##### Full name of responsible person

Dr.Masum masumpur

##### Street address

Shiraz - Zand Street - Next to the Red Crescent - Sakhtmtn Central University - Class 7 - Research

##### City

shiraz

##### Grant name

-

##### Grant code / Reference number

-

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

Yes

##### Title of funding source

Vice President of Research Shiraz 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

Shiraz University of Medical Sciences

#### Full name of responsible person

marzieh akbarzadeh

#### Position

Master of Midwifery

#### Other areas of specialty/work

#### Street address

Namazi Square, Shiraz

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Web page address**

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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*